IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 4, June 2024

Adverse Drug Reaction of Melanocyl Ointment

Mr. Prasad Gajanan Chokhande, Prof. Kiran K. Bibave
Mr. Suresh Jagdish Choudhary, Miss. Vaishanvi Ajit Gawari
SSP Shikshan Sanstha Siddhi College of Pharmacy, Chikhali, Pune, India

Abstract: *The term "adverse drug reaction" (ADR) refers to an unpleasant and inadvertent reaction T that happens at the dosage of a medication that is typically used for illness prophylaxis, diagnosis, ortherapy. Because ADRs are associated with higher rates of morbidity and mortality, they place a significant cost on contemporary society. Any class of medication might have adverse drug reactions (ADRs), and as more and more therapies become available, the likelihood of ADRs rises as well. Research indicates that children and infants experience higher rates of adverse drug*
(ADRs) than adults do, and that these reactions are typically more severe. The case study report adverse drug reaction described 41 year old patient applied Melanocyl cream after the application patient develop rashes itchiness to the hand skin. As the result health care facility the spontaneous monitoring, reporting documenting and avoid ness of ADR's since doing so is crucial to provide better health care

Keywords: Rashes, Itchiness, Melanocyl Ointment.

I. INTRODUCTION

The term "adverse drug reaction" (ADR) refers to an unpleasant and inadvertent reaction that happens at the dosage of a medication that is typically used for illness prophylaxis, diagnosis, or therapy.The majority of the time, this is because clinical trials typically have small sample sizes and poor statistical power. Consequently, the health care facility should encourage the spontaneous monitoring, reporting, documenting, and avoidance of ADRs because doing so is crucial to providing better healthcare. The research and practices around the identification, evaluation, comprehensiveion, and avoidance of side effects or any other issue pertaining to medications or vaccinations are known as pharmacovigilance. Vitiligo is a depigmenting skin condition characterized by a specific melanocyte depletion, resulting in melanin attenuation inside the skin's damaged regions. A distinguishing feature is a completely amelanotic non-scaly, chalky-white macule with clear borders. The understanding of the etiology of vitiligo has advanced significantly in recent years. It is now categorically recognized as an autoimmune disorder associated with metabolism and oxidative stress, including cellular detaching diseases, as well as hereditary and environmental factors. The consequences of vitiligo can be mentally distressing and frequently have a significant impact on daily life; thus, this should never be dismissed as an aesthetic or minor illness. The two main types of the condition recognized by a global consensus in 2011 were nonsegmental vitiligo (NSV) and segmental vitiligo (SV).

COMMON SIDE EFFECT:
• Skin rashes.
• Flushing
• Headache.
• Nausea
• Vomiting.
• Dizziness
• Increase BP and hypersensitive reaction.

HISTORY:

A review of the significance of comprehending an ADR's predictability was conducted in 1971. According to estimates, 70–80% of ADRs are predicted and might be avoided. It is true that some ADRs cannot be prevented and will still happen despite the most stringent safety measures. But a 3 sizable percentage of ADRs might be avoidable.

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 4, June 2024

Still, not enough is being done in today's hospitals to recognize and comprehend avoidable adverse drug reactions. This data is crucial for informing educational initiatives and policies that support a decrease in the quantity of ADRs that take place. One useful piece of data that may be included back into the system to speed up the process of development is the preventability of ADRs. In their routine clinical practice, nearly all doctors encounter several cases of suspected adverse cutaneous drug responses (ACDRs) in various forms. These cutaneous reactions are frequent, but because many of them go unreported, detailed information about their frequency, severity, and long-term health implications is frequently unavailable. Since a new medication is introduced into the market practically every day in the modern world, there is always a risk that an unreported new drug response may occur anywhere in the world

1. To detect the nature and frequency of ADRs
2. Providing updated Drug Safety Information to Health Care Professionals.
3. To assist the Drug regulatory authority, public health programs, scientists and consumer society to minimizeADRs.
4. To identify risk factor that may predispose, induce the development, severity andincidence of ADR.
5. Dissemination of information by designing proper education program to

CLASSIFICATION:

Adverse drug reactions can be classified into five types depending on:

1) Depending on Onset of Event: Acute.

2) Based on Type of Reactions:

I) Rawlins and Thompson classification (1991):

Type A (Augmented Reactions),
Type B (bizarre reactions),
Type C (chronic reactions),
Type D (Delayed type reactions),
Type E (end of treatment).

ii) Wills and Brown Classification:

Type A (Augmented Reactions),
Type B (bizarre reactions),
Type C (chronic/Chemical reactions),
Type D (Delayed type reactions), Type E (end of treatment),
Type F (Familial reactions),
Type G (Genotoxicity), Type H (Hypersensitivity),
Type U (Unclassified).

3) Based on Severity: Minor, Moderate, Severe, Lethal.

4) Depending on Whether They Could Take Place in Any Patient, or in a Specific Susceptible Population:

i) Reactions that might take place in anyone: Drug overdose, Drug side effect, Drug interaction.

ii) Reactions that Take Place Only in Susceptible Individuals: Drug intolerance, Drug idiosyncrasy. Drug allergy, Pseudo allergic reaction.

5) Others: Secondary effects, Toxic effects, photosensitivity, drug dependence, drug withdrawal reactions, teratogenicity, mutagenicity, carcinogenicity, drug induced disease (Iatrogenic reactions).

Severity	Description	Example
Mild	No treatment or antidote for over dosage required; longer duration hospitalization also not required.	Opioids causing constipation antihistaminic causing some drowsiness
Moderate	Specific or change In exsiccating treatment may be required but, drug is not necessarily to be discontinued (ex. Addition of drug to the regimen, dose modification)	Non-steroidal anti-inflammatory depending on onset of event; drug causes oedema and hypertension hormonal contraceptive causing venous thrombosis

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 4, June 2024

Severe	Drug reaction can cause potential life threatening event, drug and specific treatment of drug reaction must be discontinued.	Phenothiazine; abnormal heart rate ACE INHIBITOR; angioedema
Lethal	An adverse reaction can cause death of patient, either directly or indirectly	Overdose of anticoagulant; haemorrhage over dose of drug acetaminophen; liver failure

Table 1. Adverse drug reaction and classification

ADRDETECTION METHOD:

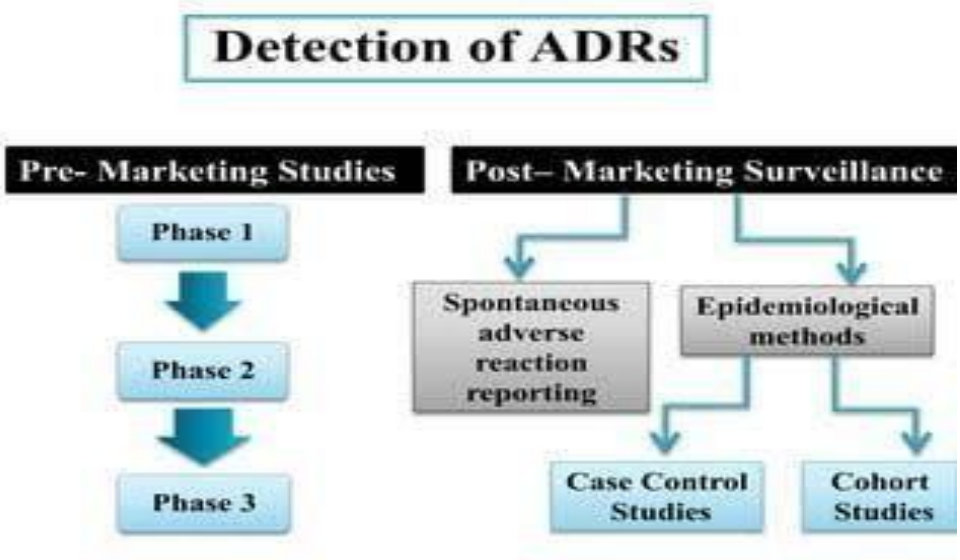


Fig.1 Detection of ADR

- Pre-marketing studies
- Post-marketing surveillance
- Assessing causality
- Communicating ADRs
- Postal Survey Method

Pre marketing study:

1. Animal models are used to assess new medication formulations for safety.
2. It is simple to obtain specific animal studies for mutagenicity, carcinogenicity, andteratogenicity.
3. Before submitting the final report to a marketing authorization application (MAA), separatephases of clinical studies are completed.
4. Clinical trials make it simple to identify ADRs with frequencies larger than 0.5–1.0%.

Post marketing surveillance.

1. Pharmacovigilance approaches are useful for both determining the risk associated with amedicine and gathering relevant data
2. A strong and reasonably priced method for identifying unknown drug related risk is thespontaneous adverse drug response reporting system.
3. ADR results (in a patient) might be viewed as a component of a health care provider'sprofessional duty report under their provision.
4. This product defect addresses and identifies issues such as drug intoxicants, drug misuse, andunanticipated absence of therapeutic impact in the drug.
5. These are the two epidemiological techniques that are frequently employed:

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 4, June 2024

Cohort Studies: Patients taking a specific medication should be actively and methodically observed, and the frequency of adverse drug reactions (ADRs) should be contrasted with a controlgroup that has not taken the medication.

Case-Control Research

It is important to identify the person who was impacted by the negative occurrence under study.Every case ought to be contrasted with multiple disease-free control patients selected at random from the research population.

It is important to determine whether the cases and controls were exposed to any potential causal agents prior to the incident.

The odd ratio needs to be computed using exposure data.

Assessing causality:

Establishing a link between a medication and a potential reaction is known as causation evaluation.

If an adverse drug response (ADR) is suspected, the evaluation process begins with gathering pertinent information about the patient's demographics,

Expert opinion from the pen.

Formal algorithms.

Communicating ADR:

The following methods are used to provide information on the responsible and sensible use of medications:

When health professionals are receiving their foundational training.

By offering ongoing training courses to medical practitioners.

Via medication information centre that have been specially designated.

By giving the patient counselling as well as inserting the package, which is a paper containinginformation about that drug and its use.

Postal survey method:

This approach consists of a particular drug-related questionnaire.

Within a year or two of a medicine's introduction, it is primarily utilized for tracking adversedrug reactions (ADRs).

Information regarding the drug, usage, dosage, brand, and number of patients treated in a specific time frame should be included in the questionnaire.

As the literature suggests, a list of the common adverse drug reactions (ADRs) should beincluded at the end of the questionnaire.

Medical professionals across the state or city who are likely to utilize the medication should getthe questionnaire by mail, along with a pre-paid envelope.

III. MANEGMENT OF ADR:

Remove any suspected drugs as the first and most important step in the management process. If the reaction is thought to be dose-related, the drug's dosage needs to be decreased, and the possibility of treating the suspected reaction needs to be taken into consideration. When managingan adverse drug reaction, it's important to keep the treatment goal clear. It is imperative that the patient get regular reviews, that the medication therapy be stopped sooner rather than later, and that simpler management techniques are implemented. The following is a frequently employed response plan when handling a suspected adverse medication reaction:

The following procedure need to be followed when managing any kind of suspected or unanticipated adverse medicationreaction.

Keeping an eye on patients who are more likely to experience ADRs. Observing individuals who are prescribed medications that have a high risk of adverse drug reactions.

1. Evaluating and recording the patient's history of allergies.
2. Evaluating whether the patient's medication regimen is appropriate
3. Varying the drug's dosage
4. Substitution with a different medication
5. Adopting a preventive routine
6. Examining potential pharmacological interactions when using several treatments
7. Support medical professionals in identifying and evaluating adverse drug reactions

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 4, June 2024

8. Encouraging medical professionals to report adverse drug reactions.
9. Recording suspicious reported reactions in order to have further references.
10. Seeking input regarding the stated response
11. Teaching medical personnel, the value of reporting an adverse drug reaction.
12. Teaching medical.

SPONTANEOUS REPORTING OF ADVERSE DRUG REACTION:

Components of ADRs Monitoring -

1. Information about the patient
2. Description of ADRs
3. Suspected drug(s)
4. Reporter

Benefits of ADR monitoring:

Accurate information regarding the safety of medications.
The mitigation of unfavourable consequences associated with medicinal products.
Education regarding ADRs and their management for the medical staff, patients, pharmacists,and nurses.

Procedure for Reporting ADRs

Only Suspected Links between a Drug and a Specific Adverse Event.
There is no proof that a drug and an ADR are causally related just because an ADR isreported.
It is preferable to report anything in dubious circumstances than not to Details Needed to Filean ADR Report
Details on the patient
ADRs
Details on Possible Drug(s)
Details about ADR Management
Details about the journalistWhat to Report :
Every adverse drug reaction (ADR) brought on by prescription and over-the counter medication.
All possible adverse drug reactions, irrespective of the company's product details
Unexpected product response, regardless of the kind or degree of the reaction
A noted rise in a specific reaction's frequency.
A significant reaction, whether anticipated or not;
All possible adverse drug reactions (ADRs) connected to interactions between drugs and food,drugs and supplements;
ADRs brought on by pharmaceutical errors or overdoses Exceptional ineffectiveness or probable medication flaws noticed.
As soon as feasible, an ADR should be reported.
A delayed report results in erroneous and untrustworthy information.

Methods for Reporting
An ADR reporting form should be used for the report.
You can get this form from www.cdsco.nic.in and www.ipc.gov.in. A. Health Information Patientinitials: Omit the patient's complete name and just write their initials. Madhu Gupta, for instance,should be written as MG.
Age at the time of the occurrence or date of birth: Record the patient's age or date of birth atthe time the event or reaction happened.
Sex: Bring up the patient's gender.
Weight: Bring up the patient's weight.Suspected Adverse Reaction:
The start date of the reaction was Mention the day that the reaction was initially seen. Date ofrecovery: If the patient's reaction was mitigated, the date of recovery needs to be documented.Explain your response: Give a detailed account of

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 4, June 2024

the reaction, including its nature, location, etc. For instance, the patient's upper and lower limbs developed an erythematous maculopapularrash.

Suspected Medication:

1. Information about any suspected medications, including the brand or generic name of the substance. The reporter should include the following information: manufacturer, batch/lot number, expiration date, dose utilized, route taken, frequency dates of therapy start and finish, and indication.
2. Requirements details: Mention the following when discussing the status of the challenge: 'Yes' for a reaction that abates after the challenge; 'No' for a reaction that did not abate afterthe challenge; 'Unknown' for an effect of the challenge that is unknown; 'Not Applicable' or 'NA' for a challenge that is not applicable, such as in the case of vaccinations, anesthesia, when a single dose is given; death; or treatment that is finished before reaction or event 'Reduced dose'. If the response happened at a dose of report.
3. Details of the challenge: State the following: 'Yes' if the reaction returned following the challenge; 'No' if it did not; 'Unknown' if the effect of the challenge was not established; 'Not Applicable' or 'NA' if the challenge was not relevant, as in the case of an anaphylacticreaction. *Reintroduced dose: State the dosage and the date of the reintroduction.
4. Concurrent medications: List all concurrent medications, including over the-counter, herbal, and self-medication medications, together with the dates of therapy.
5. Tests and laboratory data that are pertinent: If available, mention all laboratory data that are pertinent to the response that occurred.
6. Additional pertinent history: Include any pertinent medical history that the patient has maintained, such as allergies, pregnancy, smoking, alcohol consumption, hepatic or renal impairment, and any concurrent conditions that can be explained in this area.
7. Seriousness of the reaction: Check the relevant reason for seriousness as follows if the reaction is serious in nature: "Death": if a medical incident caused the patient's death Note:Depending on how terrible the reaction is, mention the cause of death and the date. *Life-threatening: If the patient had a significant chance of passing away at the time of the unfavourable incident
8. Hospitalization/prolonged' refers to an adverse incident that led to hospitalization or prolonged hospital stays for the patient; 'Disability' refers to an adverse event that significantly disrupted the person's ability to carry out regular living functions. Congenital anomaly: If drug exposure occurred before conception or during pregnancy, it could havehad a negative effect on the unborn child
9. Required intervention to prevent permanent impairment/damage' refers to situations in which a patient would require medical or surgical intervention in order to avoid lasting harm to a body structure or permanent impairment of a bodily function. "Other" refers to an occurrence that does not meet the above criteria but could still endanger the patient andnecessitate medical or surgical intervention to avoid one of the disorders listed above. Serious blood dyspraxia (blood disorders), seizures/convulsions that do not require hospitalization, and the emergence of drug dependence or misuse are a few examples.
10. Name and Professional address: The form requires the reporter to provide their name and address professionally. The reporter's name will be kept private and discreet.
11. Causalityassessment: If the reporter has received training, they must do the evaluation and provide justification for it.
12. Reporting date: Indicate the day that the unfavourable incident was reported by the individual. Gather all of the data needed to complete the suspected ADR reporting form. If all necessary information is not accessible, complete all of the EssentialRequirements (ERI) to ensure a high-quality. ICSR. Make sure the form has all the required fields even if ERI are not available. RequiredFields Patient initials, age at commencement of response, reaction term(s), date of onset of reaction, suspected medication(s) and reporter's information. The following are essentially necessary item: patient initials; age at reaction onset; gender; reaction term(s); date of reaction onset; suspected medication(s); dose; date therapy started; indication of use; seriousness; outcome; details of challenge and re challenge reporter's information; reports dates.

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 4, June 2024

AIM AND OBJECTIVES

Aims: Aim of these case report observational study of adverse drug reaction
It focus on the Adverse drug reaction of Melanocyl Ointment
Objectives: To monitor ADR in Indian population.
To generate independent, evidence based recommendations on the safe of medicines.
Primary objective: To Study the adverse drug reaction due to Melanocyl Ointment
Study Design :- observational study
Source of study population: OPD patient visited to Surya Hospital, Pune.
Sample Size:- Number of Patient admitted for Adverse drugs Reaction in Surya Hospital, Pune meeting inclusion and exclusion criteria during eight day's study period.
Inclusion: -Patient's name, age, gender.
Drug Prescribed.
Dosage of Drugs Prescribed & dosage form.
Route of Administration.
Exclusion :-
Incomplete information regarding patient

IV. STUDY MATERIAL & METHOD

CASE STUDY
Patient demographics: OPD patient came Surya hospital was admitted for vitiligo treatment, administration through topical route patient developed rashes, itchiness after few hours.
4.1Patient Information:
Patient Initials –AB
Age –41 years
Sex – Female
Hospital/Clinic – Surya Hospital, Pune
Therapy Dates:
Date Started – 01/03/2024
Date Stopped – 01/03/2024
Indication – skin
Suspected Medication Details -
Drug: Melanocyl Ointment
Batch No.-16004300
Reaction start date: 1/3/24
Reaction stop date: 1/3/24
Route – TOPICAL
Expiry date – 06/25
Frequency - OD
Indication – RASHES, ITCHING
Reporter Details
Name – Dr. SHAILESH KENDRE
Address- Clinical Pharmacologist, SURYA HOSPITAL PUNE.
Contact – 9985648650
Occupation- Clinical Pharmacologist

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 4, June 2024

SURYA HOSPITAL

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of ADRs By Healthcare Professionals
INDIAN PHARMACOPOEIA COMMISSION (National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India, Sector-23, Raj Nagar, Ghaziabad-201002
PvPI Helpline (Toll Free) : 1800-180-3024 (9.00 AM to 5.30 PM, Monday-Friday)

Initial Case ☐ Follow-up Case ☐

A. PATIENT INFORMATION *

1. Patient Initials: AB
2. Age or date of birth: 41 yrs
3. Gender: M ☐ F ☑ Other ☐
4. Weight (in Kg.)

B. SUSPECTED ADVERSE REACTION *

5. Event / Reaction start date (dd/mm/yyyy): 01/03/2024
6. Event / Reaction stop date (dd/mm/yyyy): 01/03/2024
7. Describe Event/Reaction management with details, if any

41 year female patient came with above complaints had H/O application of ointment Melanoyl to B/L hand and rash- B/L upper limb & ichtinus

FOR AMC / NCC USE ONLY

Reg. No. / IPD No. / OPD No. / CR No. :
AMC Report No. :
Worldwide Unique No. :

12. Relevant investigations with dates :

13. Relevant medical / medication history (e.g. allergies, pregnancy, addiction, hepatic, renal dysfunction etc.)

14. Seriousness of the reaction : No ☐ If Yes ☐ (please tick anyone)
☐ Death (dd/mm/yyyy) ☐ Congenital anomaly
☐ Life threatening ☐ Disability
☐ Hospitalization-Initial/Prolonged ☐ Other Medically important

15. Outcome:
☐ Recovered ☐ Recovering ☐ Not Recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S) *

S. No.	B. Name (Brand/ Generic)	Manufacturer (if known)	Batch No. / Lot No.	Expiry Date (if known)	Dose	Route	Frequency	Therapy Dates: Date Started	Therapy Dates: Date Stopped	Indication	Causality Assessment
i	Melanoyl				-	Topical	OD	1/03/24	1/03/24	Rash	6
ii											
iii											
iv#											

9. Action taken after reaction (please tick)

S. No. as per C	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown
i	Melanoyl				Topical	
ii						
iii						
iv						

10. Reaction reappeared after reintroduction of suspected medication (please tick)

Yes	No	Effect unknown	Dose (if re-introduced)

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S. No.	Name (Brand / Generic)	Dose	Route	Frequency (OD, BD, etc.)	Therapy Dates: Date Started	Therapy Dates: Date Stopped	Indication
i							
ii							
iii#							

Additional Information :

D. REPORTER DETAILS *

16. Name & Address : Dr. Shailesh Kendre
Pin : _____ Email : _____
Contact No- : _____
Occupation : GP Signature : _____

17. Date of this report (dd/mm/yyyy) :

Signature and Name of Receiving Personnel :

Confidentiality : The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

Use separate page for more information
* Mandatory Fields for suspected ADR Reporting Form

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 4, June 2024

SUSPECTED MEDICINE -

ABOUT MELANOCYL OINTMENT

MELANOCYL OINTMENT belongs to the dermatological medication class primarily used in treating vitiligo. Skin cells or melanocytes are responsible for making skin color by producing melanin. In vitiligo, melanocytes lose their function or are destroyed, leaving white patches on the skin. Vitiligo can affect any skin area; however, it typically affects the face, neck, hands, and skin creases.

MELANOCYL OINTMENT is a combination of two drugs: Methoxsalen and Aminobenzoic Acid. MELANOCYL OINTMENT helps melanocytes to resume their natural function, resulting in uniform natural skin color. Thereby, MELANOCYL OINTMENT helps in treating vitiligo. MELANOCYL OINTMENT protects against sunburn and helps to prevent premature skin ageing. It also regulates the overgrowth of skin cells and decreases the proliferation of cells.

Apply the ointment to the skin as directed by your doctor. Irritation, burning sensation, itching, and redness of the skin at the application site are the common side effects of MELANOCYL OINTMENT. These side effects do not necessitate medical treatment and will fade away with time. Do not hesitate to contact your doctor if these side effects persist.

Medicinal Benefits

MELANOCYL OINTMENT is a dermatological medication that is primarily used to treat vitiligo. It can also help to prevent sunburns and slow down the ageing process. MELANOCYL OINTMENT is a combination of two drugs: Methoxsalen and Aminobenzoic acid. MELANOCYL OINTMENT helps melanocytes resume their natural function, resulting in uniform natural skin color. As a result, MELANOCYL OINTMENT contributes to the treatment of vitiligo. It also protects against sunburn and helps to prevent premature skin ageing by absorbing harmful ultraviolet (UV) radiation.

Directions for Use

MELANOCYL OINTMENT is only for external use. Take a small amount of MELANOCYL OINTMENT on the fingertip and apply it as a thin layer on the clean and dry affected area as prescribed by your doctor. Avoid contact of the MELANOCYL OINTMENT with the nose or eyes. In case of accidental contact with these areas, rinse with water thoroughly. Wash your hands before and after using MELANOCYL OINTMENT if your hands are not the affected area to prevent the spread of infection.

Drug Interactions

Drug-Drug Interactions: MELANOCYL OINTMENT may interact with photo sensitizing agents (e.g. aminolevulinic acid).

Drug-Food Interactions: Avoid or limit the consumption of red meat, nightshades, citrus fruits, processed foods.

Drug-Disease Interactions: Let your doctor know before using MELANOCYL OINTMENT if you have a photosensitive disease and skin cancer.

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 4, June 2024

Drug-Drug Interactions Checker List

AMINOLEVULINIC ACID

A medication used to treat psoriasis, eczema, vitiligo, and some cutaneous lymphomas in conjunction with exposing the skin to ultraviolet (UVA) light from lamps or sunlight. Methoxsalen modifies the way skin cells receive the UVA radiation, allegedly clearing up the disease. Levels of individual patient PUVA exposure were originally determined using the Fitzpatrick scale. The scale was developed after patients demonstrated symptoms of Photo toxicity after oral ingestion of Methoxsalen followed by PUVA therapy. Chemically, Methoxsalen belongs to a class of organic natural molecules known as furanocoumarins. They consist of Coumarin annulated with furan. It can also be injected and used topically.

Score	Interpretation on score	The Reaction
Total score >9	Definite	The Reaction followed a reasonable sequence after a drug or in which a toxic drug level had been established in body fluids or tissues, followed a recognized response to the suspected drug, and was confirmed by improvement on withdrawing the drugand reappeared on re exposure.
Total score 5 to 8	Probable	The reaction followed a reasonable temporal sequence after a drug, followed a recognized response to the suspected drug, was confirmed by withdrawal but not by exposure to thedrug, and could not be reasonably explained by the knowncharacteristics of the patient's clinical state.
Total score1 to 4	Possible	The reaction 1)followed a temporal sequence after a drug, possibly followed a recognized pattern to the suspected drug, and Could be explained by characteristics of the patient'sdisease.
Total score < 0	Doubtful	The reaction was likely related to factors other than a drug.

The Scale is classified as:

1. Mild: A reaction that does not required treatment or hospital stay.
2. Moderate: A reaction that requires treatment and or prolongs hospitalization by at least one day.
3. Severe: A reaction that is potentially life threatening or contributes to the death of patient is

Permanently disabling requires intensive medical care or results in a congenital anomaly cancer or unintentional overdose.

To study the onset of ADRs:

1. Acute: Acute events are those which are observed within 60 minutes after the administration of medication.
2. Sub-Acute: These occur within 1-24 hours from the time f administration of medication.
3. Latent: These reaction take 2 more days to become apparent.

Preventability of ADRs:

Complete preventability of ADR is not possible, but some of the ADR can be preventable if that
ADR can give at least one answer of Schumock and Thornton Scale.

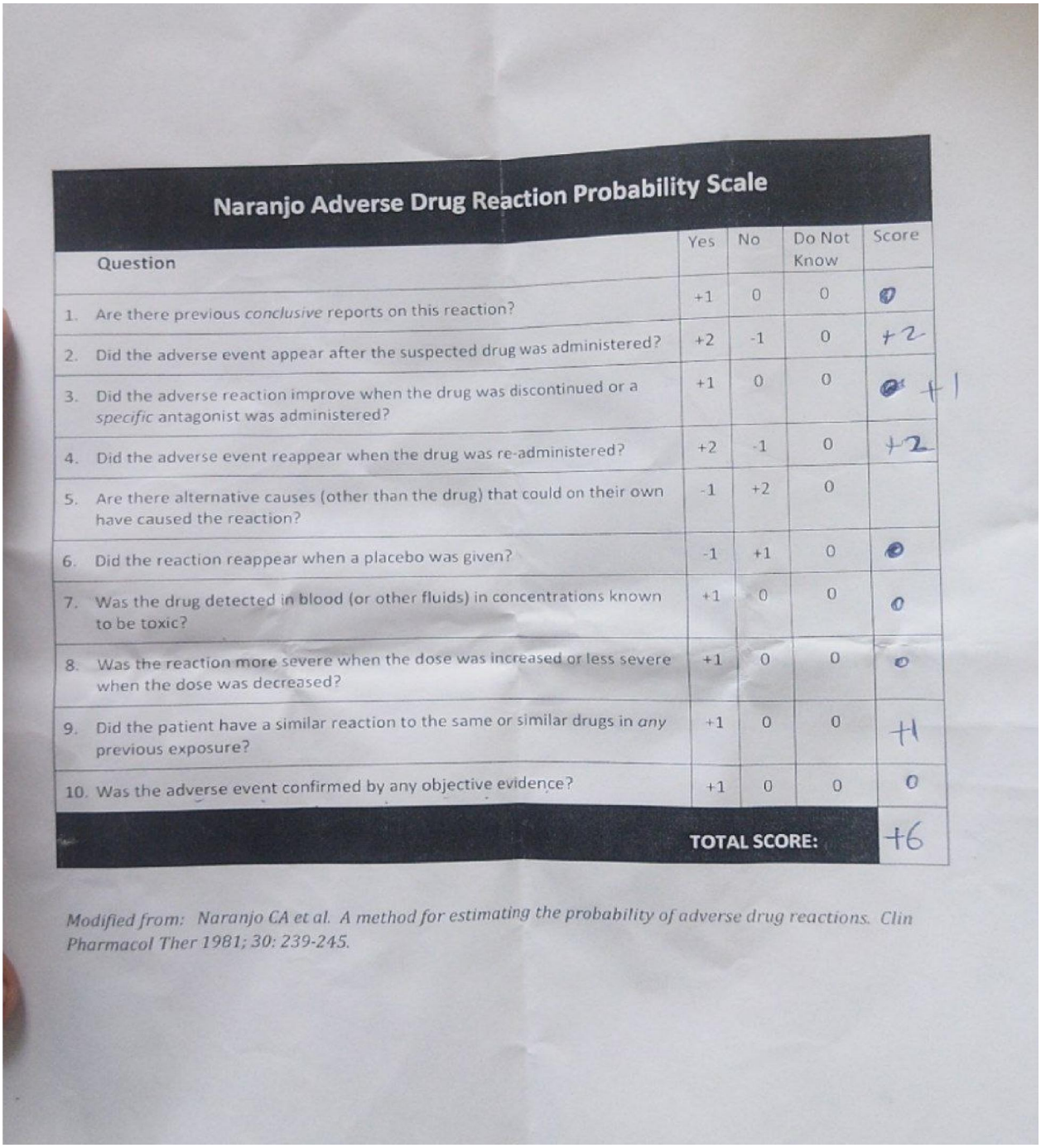
Predictability of ADRs:

Patients who have had the drug on previous occasion(s): If the drug was previously well-tolerated at the same dose and route of administration, the ADR is NOT PREDICTABLE; there was a history of allergy or previous reaction to the drug, the ADR is PREDICTABLE. Patients who have never had the drug previously: Incidence of the ADR reported in product information or other literature determines its predictability.

V. RESULT

The scale of NARANJO Scale for case report of adverse drug reaction (ADR) of Melanocyl Ointment OPD patient is 6 it suggest probable casual relation between medication and ADR the need of ADR reporting in tertiary hospital to help in assessing benefit risk ratio of drug from the study it has been concluded that incidence of ADR occur due to application of Melanocyl Ointment.

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 4, June 2024



Naranjo Adverse Drug Reaction Probability Scale

Question	Yes	No	Do Not Know	Score
1. Are there previous *conclusive* reports on this reaction?	+1	0	0	0
2. Did the adverse event appear after the suspected drug was administered?	+2	-1	0	+2
3. Did the adverse reaction improve when the drug was discontinued or a *specific* antagonist was administered?	+1	0	0	0 +1
4. Did the adverse event reappear when the drug was re-administered?	+2	-1	0	+2
5. Are there alternative causes (other than the drug) that could on their own have caused the reaction?	-1	+2	0	
6. Did the reaction reappear when a placebo was given?	-1	+1	0	0
7. Was the drug detected in blood (or other fluids) in concentrations known to be toxic?	+1	0	0	0
8. Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	0
9. Did the patient have a similar reaction to the same or similar drugs in *any* previous exposure?	+1	0	0	+1
10. Was the adverse event confirmed by any objective evidence?	+1	0	0	0
			TOTAL SCORE:	+6

Modified from: Naranjo CA et al. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther 1981; 30: 239-245.

VI. DISCUSSION:

MELANOCYL OINTMENT belongs to the dermatological medication class primarily used in treating vitiligo. Skin cells or melanocytes are responsible for making skin color by producing melanin. In vitiligo, melanocytes lose their function or are destroyed, leaving white patches on the skin. Vitiligo can affect any skin area; however, it typically affects the face, neck, hands, and skin creases.

MELANOCYL OINTMENT is a combination of two drugs: Methoxsalen and Aminobenzoic Acid. MELANOCYL OINTMENT helps melanocytes to resume their natural function, resulting in uniform natural skin color. Thereby, MELANOCYL OINTMENT helps in treating vitiligo. MELANOCYL OINTMENT protects against sunburn and helps to prevent premature skin ageing. It also regulates the overgrowth of skin cells and decreases the proliferation of cells.

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 4, June 2024

41 year old patient come to hospital for ADR symptom of Melanocyl ointment was administered. Patient developed rashes and itching to the skin after application ointment within few hours in present study Naranjo was measured 6, its states that type of adverse drug reaction is probable adverse drug reaction type. The study shows that the patient
Developed rashes and itchiness after application of Melanocyl so its states that there is the causality assessment in between adverse drug reaction and suspected medicine

VII. CONCLUSION:

The given case report concluded that the patient prescribed with ointment Melanocyl develop adverse drug reaction like rashes and itchiness to skin after few hour its states that there is causality assessment between suspected medication and adverse drug reaction. The score of Naranjo scale was 6, its state that adverse drug reaction type is probable adverse drug reaction type .

Healthcare professionals should be aware of the potential for ADRs and be prepared to manage them appropriately, including promptly recognizing and discontinuing the offending medication if necessary. Overall, this case report highlights the importance of pharmacovigilance in monitoring patients for adverse drug reactions, spontaneous reporting particularly when introducing new medications or observing unexpected symptoms. It also emphasizes the need for further research and investigation to better understand the specific risk factors and mechanisms underlying adverse reactions to medications like Melanocyl Ointment Further investigation, may be warranted to confirm the specific drug allergy and determine whether Ointment Melanocyl should be avoided in the future. Healthcare professionals should also consider documenting and reporting this adverse drug reaction to relevant pharmacovigilance systems, contributing to the overall understanding and monitoring of drug safety profiles. Further investigation is needed.

REFERENCES

[1]. Ezzedine K, Lim HW, Suzuki T, Katayama I, Hamzavi I, Lan CC, et al. Revised classification/nomenclature of vitiligo and related issues: the Vitiligo Global Issues Consensus Conference. Pigment Cell Melanoma Res. 2012;25:E1–E13.
[2]. Silva de Castro CC, do Nascimento LM, Olandoski M, Mira MT. A pattern of association between clinical form of vitiligo and disease-related variables in a Brazilian population. J Dermatol Sci. 2012;65:63–67.
[3]. Lin JY, Fisher DE. Melanocyte biology and skin pigmentation. Nature. 2007;445:843–850.
[4]. Westerhof W. The discovery of the human melanocyte. Pigment Cell Res. 2006;19:183–193.
[5]. Lee AY, Kim NH, Choi WI, Youm YH. Less keratinocyte-derived factors related to more keratinocyte apoptosis in depigmented than normally pigmented suctionblistered epidermis may cause passive melanocyte death in vitiligo. J Invest Dermatol. 2005;124:976–983.
[6]. Fitzpatrick TB. Dermatology in general medicine. 4th ed. New York: McGraw-Hill; 1993.
[7]. Haass NK, Herlyn M. Normal human melanocyte homeostasis as a paradigm for understanding melanoma. J Investig Dermatol Symp Proc. 2005;10:153–163
[8]. Carlson JA, Linette GP, Aplin A, Ng B, Slominski A. Melanocyte receptors: clinical implications and therapeutic relevance. Dermatol Clin. 2007;25:541–557.:
[9]. Moretti S, Spallanzani A, Amato L, Hautmann G, Gallerani I, Fabiani M, et al. New insights into the pathogenesis of vitiligo: imbalance of epidermal cytokines at sites of lesions. Pigment Cell Res. 2002;15:87–92.
[10]. Le Poole IC, Das PK. Microscopic changes in vitiligo. Clin Dermatol. 1997;15:863–873
[11]. Le Poole IC, van den Wijngaard RM, Westerhof W, Dutrieux RP, Das PK. Presence or absence of melanocytes in vitiligo lesions: an immunohistochemical investigation. J Invest Dermatol. 1993;100:816–822.
[12]. Tobin DJ, Swanson NN, Pittelkow MR, Peters EM, Schallreuter KU. Melanocytes are not absent in lesional skin of long duration vitiligo. J Pathol. 2000;191:407–416.