Anthisan® Cream

SANOFI

SCHEDULING STATUS: S2
PROPRIETARY NAME (and dosage form):
ANTHISAN® CREAM
COMPOSITION:
ANTHISAN Cream contains:
Mepyramine maleate 2 g/100 g
Preservative: Methyl hydroxybenzoate 0,2 % m/m
Contains tartrazine.
PHARMACOLOGICAL CLASSIFICATION:
A 5.7.1 Antihistamines.
PHARMACOLOGICAL ACTION:
Mepyramine maleate is an active antihistamine agent which has also been shown experimentally to possess local analgesic activity. It is metabolised fairly quickly in the body.
INDICATIONS:
The cream is used for relief of itching and painful skin conditions, especially those associated with bites and stings due to insects and jellyfish. It also relieves the irritation and pain of nettle rash and unbroken chilblains. The cream is a useful first-aid dressing for sunburn and for minor scalds and burns.
CONTRA-INDICATIONS:
Mepyramine is contra-indicated in premature infants or neonates. Acute vesicular and exudative dermatoses.
Use with occlusive dressings.
Use on broken skin and in patients hypersensitive to mepyramine. Safety in pregnancy and lactation has not been established.
WARNINGS:
ANTHISAN Cream contains tartrazine which may cause allergic type reactions (including bronchial asthma) in certain individuals. The overall incidence of tartrazine sensitivity is low; it is frequently seen in patients who also have aspirin sensitivity.
DOSAGE AND DIRECTIONS FOR USE:
FOR EXTERNAL USE ONLY.
ANTHISAN Cream should be applied to the affected area two or three times daily for up to three days. Special care must be taken when large areas of broken skin are involved, and application must be discontinued immediately if there is an adverse skin reaction due to sensitisation to the product.
SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
Topical therapy may produce hypersensitivity reactions, particularly of the skin, and cross-sensitivity to related drugs may occur.
Skin sensitisation, eczematous reactions and photosensitivity may develop after topical application.
Systemic side-effects have been reported after topical application of antihistamines to large areas of the skin.
KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Overdose may be fatal especially in infants and children. Overdosage is associated with antimuscarinic, extrapyramidal, gastrointestinal and central nervous system effects. In infants and children, central nervous system stimulation predominates over central nervous system depression, causing ataxia, excitement, tremors, psychoses, hallucinations, and convulsions; hyperpyrexia may also occur. Deepening coma and cardiorespiratory collapse may follow. In adults, central nervous system depression is more common with drowsiness, coma and convulsions, progressing to respiratory failure or possibly cardiovascular collapse.
In severe overdosage with antihistamines the stomach should be emptied. Emetics may be tried if the patient is alert and there are no symptoms of toxicity, but may be ineffective due to the anti-emetic activity of the antihistamine. Activated charcoal has been given, as have saline laxatives. Convulsions may be controlled with diazepam, although it has been suggested that central nervous system depressants should be avoided. Central stimulants may increase the risk of convulsions, and their avoidance is advisable.
Further treatment is supportive and symptomatic.
IDENTIFICATION:
A smooth, homogenous, pale green cream.
PRESENTATION:
Tubes of 25 g.
STORAGE INSTRUCTIONS:
Store below 25 ºC.
Protect from light.
Keep out of reach of children.
APPLICATION NUMBER:
G1340 (Act 101 /1965)
NAME AND BUSINESS ADDRESS OF APPLICANT:
sanofi-aventis south africa (pty) ltd
2 Bond Street, Midrand, 1685, South Africa
DATE OF PUBLICATION OF THIS PACKAGE INSERT:
August 1970

694378

Anthisan® Room

SANOFI

SKEDULERINGSTATUS: S2
EIENDOMSNAAM (en doseervorm):
ANTHISAN® ROOM
SAMESTELLING:
ANTHISAN Room bevat:
Mepiramienmaleaat 2 g/100 g
Preserveermiddel: Metielhidroksibensoaat 0,2 % m/m
Bevat tartrasien.
FARMAKOLOGIESE KLASSIFIKASIE:
A 5.7.1 Antihistaminika.
FARMAKOLOGIESE WERKING:
Mepiramienmaleaat is 'n aktiewe antihistamienmiddel, wat ook eksperimenteel aangetoon het dat dit plaaslike pynstillende aktiwiteit besit. Dit word betreklik vinnig in die liggaam gemetaboliseer.
INDIKASIES:
Die room word gebruik vir die verligting van jeukende en pynlike veltoestande, veral dié wat geassosieer is met byt- en steekplekke van insekte en jellievisse. Dit verlig ook die prikkeling en pyn van netelroos en ongebarste winterhande en -voete. Die room is nuttig vir die eerstehulpbehandeling van sonbrand en ook vir ligte nat en droë brandwonde.
KONTRA-INDIKASIES:
Mepiramien is teenaangedui in vroeggebore babas en pasgeborenes.
Akute vesikulêre en eksudatiewe dermatose.
Gebruik met afsluitdekkings.
Gebruik op stukkende vel en in pasiënte hipersensitief vir mepiramien.
Veiligheid tydens swangerskap en laktasie is nog nie vasgestel nie.
WAARSKUWINGS:
ANTHISAN Room bevat tartrasien wat in sekere individue allergiese tipe reaksies mag veroorsaak (insluitende brongiale asma). Die totale voorkoms van tartrasiensensitiwiteit is laag; dit word dikwels gesien in pasiënte wat ook 'n aspiriensensitiwiteit het.
DOSIS EN GEBRUIKSAANWYSINGS:
SLEGS VIR UITWENDIGE GEBRUIK.
ANTHISAN Room behoort twee of driemaal daagliks vir tot drie dae aan die aangetaste dele aangewend te word. Spesiale aandag moet gegee word indien daar groot areas stukkende vel betrokke is, en die aanwending moet onmiddellik gestaak word indien daar enige ongewenste reaksie intree as gevolg van sensitisering teenoor die produk.
NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
Topikale behandeling kan hipersensitiwiteitsreaksies van veral die vel, voortbring; kruissensitiwiteit teenoor verwante middels kan voorkom.
Vel sensitisering, eksemateuse reaksies en fotosensitiwiteit kan voorkom na plaaslike aanwending.
Sistemiese newe-effekte is aangemeld na plaaslike aanwending van antihistamiene op groot dele van die vel.
BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Oordosering kan dodelik wees veral by babas en kinders. Oordosering is met antimuskariniese, ekstrapiramidale, gastrointestinale en sentrale senuweestelsel effekte geassosieer. By babas en kinders, oorheers sentrale senuweestelsel stimulasie die sentrale senuweestelsel onderdrukking, en lei dit tot ataksie, opgewondenheid, bewing, psigose, hallusinasies en konvulsies; hiperpireksie kan ook voorkom. Verdiepende koma en kardiorespiratoriese ineenstorting kan volg. By volwassenes, is sentrale senuweestelsel onderdrukking met lomerigheid, koma en konvulsies, wat lei tot respiratoriese versaking en moontlike kardiovaskulêre ineenstorting, meer algemeen.
In erge oordosering met antihistamiene moet die maag geledig word. Braakmiddels kan probeer word indien die pasiënt wakker is en daar geen simptome van toksisiteit is nie, maar dit kan oneffektief wees a.g.v. die braakwerende werking van die antihistamien.
Geaktiveerde houtskool is al toegedien, so ook sout lakseermiddels.
Konvulsies kan beheer word met diasepam, alhoewel daar voorgestel word dat sentrale senuweestelselonderdrukkers vermy moet word. Sentrale stimulante kan die risiko van konvulsies verhoog en daar word aangeraai dat hulle vermy moet word.
Verdere behandeling is ondersteunend en simptomaties.
IDENTIFIKASIE:
'n Gladde, homogene, ligte groen room.
AANBIEDING:
Buise van 25 g.
BERGINGSAANWYSINGS:
Bewaar benede 25 °C.
Beskerm teen lig.
Hou buite bereik van kinders.
AANSOEKNOMMER:
G1340 (Wet 101/1965)
NAAM EN BESIGHEIDSADRES VAN APPLIKANT:
sanofi-aventis south africa (edms) bpk
Bondstraat 2, Midrand, 1685, Suid-Afrika
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