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Norflex® Gel

SCHEDULING STATUS
S1
PROPRIETARY NAME AND DOSAGE FORM
NORFLEX GEL

COMPOSITION
Each 100 g contains: Benzydamine hydrochloride 3,0 g.
Other ingredients include glycerol, hydroxyethyl cellulose, isopropyl alcohol, lavender perfume and purified water.

PHARMACOLOGICAL CLASSIFICATION
A 3.1 Antirheumatics (anti-inflammatory) agents

PHARMACOLOGICAL ACTION
Benzydamine hydrochloride is a non-steroidal, anti-inflammatory agent and exerts a local anti-inflammatory, and analgesic action.
NORFLEX GEL is well absorbed through the skin.

INDICATIONS
NORFLEX GEL is recommended as a short-term treatment for the symptomatic relief of painful inflammatory conditions of the musculo-skeletal system, including:
Acute inflammatory conditions such as myalgia and bursitis.
Traumatic conditions such as sprains, strains, contusions and the after-effects of fractures.

CONTRAINDICATIONS
Hypersensitivity to benzydamine hydrochloride.
Safety in pregnancy and lactation has not been established.

WARNINGS AND SPECIAL PRECAUTIONS
Avoid contact with eyes and mucosal surfaces.

DOSAGE AND DIRECTIONS FOR USE
NORFLEX GEL should be massaged lightly into the area three times daily, up to six times daily in more severe conditions (at the discretion of your doctor).
35 to 85 mm (1 to 2,5 g) should be used for each application.
Do not use continuously for longer than 10 days without consulting your doctor.

SIDE EFFECTS
Photosensitivity reactions have been reported.
Local skin reactions ranging from erythema to papular eruptions.
The skin may return to normal on stopping treatment.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
See **SIDE EFFECTS.**
On accidental ingestion, the following symptoms may appear:
Tissue numbness, a stinging or burning sensation, lightheadedness, nausea, vomiting and an altered sense of taste.
Treatment is symptomatic and supportive.

IDENTIFICATION
Clear colourless to slightly opalescent gel with an odour of lavender or isopropyl alcohol.

PRESENTATION
White aluminium laminated tubes containing 30 g or 75 g.

STORAGE INSTRUCTIONS
Store at or below 30 °C.
Protect from light.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER
32/3.1/0547

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
iNova Pharmaceuticals (Pty) Ltd
15E Riley Road, Bedfordview, 2007

DATE OF PUBLICATION OF THIS PACKAGE INSERT
26 September 2001

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SKEDULERINGSTATUS
S1
EIENDOMSNAAM EN DOSEERVORM
NORFLEX GEL

SAMESTELLING
Elke 100 g bevat: Bensidamienhidrochloried 3,0 g.
Ander bestanddele sluit gliserol, hidroksie etielsellulose, isopropiel alkohol, laventel geur en gesuiwerde water in.

FARMAKOLOGIESE KLASSIFIKASIE
A 3.1 Rumatiek (anti-inflammatoriese) middels

FARMAKOLOGIESE WERKING
Bensidamienhidrochloried is 'n nie-steroïdale, anti-inflammatoriese agent wat 'n plaaslike anti-inflammatoriese en analgetiese aksie uitoefen.
NORFLEX GEL word goed deur die vel geabsorbeer.

INDIKASIES
NORFLEX GEL is aangedui as kort-termyn behandeling vir die simptomatiese verligting van pynlike inflammatoriese kondisies van die muskulo-skeletale sisteem, insluitende:
Akute inflammatoriese toestande soos mialgie en bursitis.
Traumatiese toestande soos verstuiting, verrekking, kneusing en die nagevolge van frakture.

KONTRA-INDIKASIES
Hipersensitiwiteit vir bensidamienhidrochloried.
Die veiligheid in swangerskap en laktasie is nie vasgestel nie.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS
Vermy kontak met die oë en slymvliese.

DOSIS EN GEBRUIKSAANWYSINGS
Masseer **NORFLEX GEL** liggies in die area in drie keer per dag of tot ses keer per dag in meer ernstige toestande (volgens die dokter se diskressie). 35 tot 85 mm (1 tot 2,5 g) behoort gebruik te word met elke aanwending.
Moet nie aaneenlopend vir langer as 10 dae gebruik sonder om 'n dokter te spreek nie.

NEWE-EFFEKTE
Fotosensitiwiteits reaksies is al gerapporteer.
Plaaslike vel reaksies varieer van eriteem tot papulêre uitslae.
Die vel mag na normaal terugkeer met staking van die behandeling.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
Sien **NEWE-EFFEKTE.**
As dit per ongeluk ingesluk word, kan die volgende simptome tevore kom:
Weefsel verdowing, 'n steek of brand sensasie, lighoofdigheid, naarheid, braking en 'n veranderde sin van smaak.
Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE
Helder, kleurlose tot effens melkerige jel met 'n reuk van laventel of isopropiel alkohol.

AANBIEDING
Wit, aluminium, gelamineerde buise bevattend 30 g of 75 g.

BERGINGSAANWYSINGS
Bewaar teen of benede 30 ºC.
Beskerm teen lig.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER
32/3.1/0547

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT
iNova Pharmaceuticals (Pty) Ltd
Rileyweg 15E, Bedfordview, 2007

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