PC: 7822

Norflex®

SKEDULERINGSTATUS S2

EIENDOMSNAAM EN DOSEERVORM
NORFLEX Tablette

SAMESTELLING
Elke tablet bevat 100 mg Orfenadriensitraat. Ander bestanddele sluit etielsellulose, magnesiumstearaat en kolloïdale silika in. Bevat suiker (Laktose).

FARMAKOLOGIESE KLASSIFIKASIE
A 2.10 (Sentraalwerkende spierverslappers)

FARMAKOLOGIESE WERKING
NORFLEX het 'n swak antihistamieniese uitwerking en 'n geringe plaaslike verdowings effek. Geeneen van die twee is van praktiese belang nie. Die belangrikste effek is die verslapping van skeletspierspasma sonder om die normale tonus van die spiere te affekteer. Dit word toegeskryf aan die sentrale effek van **NORFLEX**. **NORFLEX** het ook 'n ligte euforiese uitwerking. **NORFLEX** verlig die pyn wat deur die spasma veroorsaak word deur die verslapping van skeletspiere.

INDIKASIES
Toestande wat skeletspierspasma veroorsaak, soos pyn in die lae rug en nek-wringing, asook dié wat die gevolg is van trauma soos sweepslagbeserings.

KONTRA-INDIKASIES
NORFLEX moet met versigtigheid voorgeskryf word vir pasiënte wat aan gloukoom, tagikardie en urienretensie ly. Die veilige gebruik gedurende swangerskap is nog nie vasgestel nie, daarom moet **Norflex** nie gebruik word deur swanger vroue nie.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS
Geen. Bevat laktose. Pasiënte met die oorerflike kondisie van galaktose intoleransie byvoorbeeld galaktosemie, Laplander laktase tekort, glukose-galaktose wanabsorpsie of fruktose intoleransie moet nie **NORFLEX** gebruik nie.

DOSIS EN GEBRUIKSAANWYSINGS
Een tablet twee of drie maal per dag.

NEWE-EFFEKTE
Newe-effekte kom na vore alleenlik wanneer groot dosisse geneem word en bestaan hoofsaaklik uit versteurde visie, droogheid van die mond en urienretensie. Hierdie newe-effekte word toegeskryf aan die anticholinergiese effek van **NORFLEX**.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
Selfs ernstige oordoserings het geen toksiese reaksies in pasiënte tot gevolg gehad nie. Die simptome van oordosering is atropienagtig, en moet aan die anticholinergiese effek van **NORFLEX** toegeskryf word. Die behandeling is simptomaties, nadat die normale voorsorgmaatreëls, nl. maagspoeling, getref is.

IDENTIFIKASIE
Wit, ronde, bikonvekse tablette gestempel N/X.

AANBIEDING
Wit plastiek bottel met 'n skroefdop wat 50 of 20 tablette bevat.

BERGINGSAANWYSINGS
Bewaar teen of benede 30 °C.
HOU BUITE BEREIK VAN KINDERS.

VERWYSINGSNOMMER
H1612 (Wet 101/1965)

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

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET
21 Februarie 1985

Norflex®

SCHEDULING STATUS S2

PROPRIETARY NAME AND DOSAGE FORM
NORFLEX Tablets

COMPOSITION
Each tablet contains 100 mg Orphenadrine citrate. Excipients include ethyl cellulose, magnesium stearate and colloidal silica. Contains sugar (Lactose).

PHARMACOLOGICAL CLASSIFICATION
A 2.10 (Centrally active muscle relaxants)

PHARMACOLOGICAL ACTION
NORFLEX has a weak antihistaminic action and a mild local anaesthetic effect, neither of which are of practical importance. Its most important action is that of relaxing skeletal muscle spasm, without affecting normal muscle tone. This results from the central action of **NORFLEX**. **NORFLEX** also exerts a mild euphoriant action. By relaxing skeletal muscle spasm, **NORFLEX** will alleviate pain resulting from the spasm.

INDICATIONS
Conditions involving skeletal muscle spasm such as low back pain and torticollis and also those resulting from trauma such as whiplash injury.

CONTRAINDICATIONS
NORFLEX should be used with caution in the presence of glaucoma, tachycardia and urinary retention. Safe use in pregnancy has not been established; therefore N**orflex** should not be used in pregnant women.

WARNINGS AND SPECIAL PRECAUTIONS
None. Contains lactose. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take **NORFLEX**.

DOSAGE AND DIRECTIONS FOR USE
One tablet two or three times daily.

SIDE EFFECTS
Side effects usually occur at higher doses only and consist of blurring of vision, dryness of the mouth and urinary retention. These result from the anticholinergic action of **NORFLEX**.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Even gross overdosage in persons has produced no serious toxic reactions. The symptoms produced are atropine-like and result from the anticholinergic action of **NORFLEX**. Treatment is symptomatic after the normal precaution of gastric lavage has been taken.

IDENTIFICATION
White, round, biconvex tablets marked N/X.

PRESENTATION
White, plastic bottles with a screw cap containing 50 or 20 tablets.

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

REFERENCE NUMBER
H1612 (Act 101/1965)

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
21 February 1985

NAMIBIA	**BOTSWANA**
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