Norflex® Co

SKEDULERINGSTATUS S2
EIENDOMSNAAM EN DOSEERVORM
NORFLEX® CO Tablette

SAMESTELLING
Elke tablet bevat 35 mg Orfenadriensitraat en 450 mg Parasetamol. Ander bestanddele sluit kolloïdale silikondioksied, magnesiumstearaat, mikrokristallyne sellulose en pregelatiniseerde stysel in. SUIKER VRY.
FARMAKOLOGIESE KLASSIFIKASIE
A 2.9 (Ander analgetika)
FARMAKOLOGIESE WERKING
Orfenadrien is 'n anticholinergiese middel. Dit het ook swak antihistamieniese, plaaslike verdowings en skeletspier-verslappende eienskappe.
Parasetamol het pynstillende en koorswerende eienskappe.
INDIKASIES
Om pyn te verlig as gevolg van spasma van die willekeurige spiere en vir die simptomatiese behandeling van ligte tot gemiddelde pyn en/of koors.
KONTRA-INDIKASIES
NORFLEX CO moet met versigtigheid gebruik word in die teenwoordigheid van tagikardie, urienterughouding en myasthenia gravis.
Dit is gekontra-indikeer in pasiënte met prostaatvergroting en moet met versigtigheid gebruik word deur ouer mans. Dit is ook gekontra-indikeer in pasiënte wat ly aan paralitiese ileus of piloriese stenose omdat die gebruik daarvan tot obstruksie kan ly.
Dit moet nie aan pasiënte met nou-hoek gloukoom of aan pasiënte met 'n noue hoek tussen die iris en die kornea gegee word nie aangesien dit die intra-okulêre druk kan verhoog. Die risiko is groter by pasiënte ouer as 40 jaar.
Dit moet nie gegee word aan pasiënte, veral kinders, wanneer die omliggende temperatuur hoog is nie, vanweë die risiko om hiperpireksie te veroorsaak.
Dit moet met versigtigheid gebruik word in pasiënte wat koors het. Dit moet met versigtigheid gebruik word in toestande wat gekenmerk word aan tagikardie soos tirotoksikose, kardiale gebrek of hartversaking en in hartchirurgie.
Die veilige gebruik gedurende swangerskap is nog nie vasgestel nie, daarom moet **Norflex Co** nie gebruik word deur swanger vroue nie.
Sensitiwiteit vir enige van die bestanddele. Ernstige ingekorte lewerfunksie.
WAARSKUWINGS
Moet nie vir meer as 10 dae aaneenlopend gebruik sonder om u geneesheer te raadpleeg nie.
Doserings groter as die voorgeskrewe, kan lewerskade veroorsaak. Pasiënte wat ly aan lewer- of niersiektes moet parasetamol onder mediese toesig neem.
Raadpleeg 'n geneesheer indien geen verligting met die voorgeskrewe dosis verkry word nie.
DOSIS EN GEBRUIKSAANWYSINGS
Volwassenes: Twee tablette drie of vier maal per dag.
NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS
Newe-effekte as gevolg van anticholinergiese werking:
Droë mond en moeilikheid om te sluk, dilatasie van die pupille, verlies van akkommodasie en fotofobie, verhoging van intra-okulêre druk, blosing en droë vel, verbygaande bradikardie gevolg deur tagikardie met palpitasies en aritmieë en die behoefte om te urineer met die onvermoë om dit te doen, asook 'n vermindering in die tonus en motiliteit van die gastro-intestinale kanaal wat lei tot hardlywigheid. Van tyd tot tyd kan braking, duiseligheid en wankelrigheid voorkom. Retrosternale pyn kan voorkom as gevolg van vermeerderde gastriese refluks. Slaaploosheid is gerapporteer. Verstandelike verwarring, veral in ouer persone. Verminderde brongiale afskeiding kan geassosieer word met mukusproppe.
Persone met Down sindroom kan meer vatbaar wees, terwyl diegene met albinisme meer weerstandig kan wees.
Die effekte van anticholinergiese middels word versterk deur die gelyktydige inname van middels wat anticholinergiese eienskappe het soos amantadien, sommige antihistamiene, butirofenone, fenotiasiene en trisikliese anti-depressante.
Orfenadrien is al misbruik vir sy veronderstelde euforiese effek.
Newe-effekte as gevolg van parasetamol:
Veluitslae en ander allergiese reaksies kan voorkom. Die uitslag is gewoonlik eritemateus of urtikariaal, maar soms meer ernstig en kan gepaard gaan met koors en slymvliesletsels. Die gebruik van parasetamol word geassosieer met die voorkoms van neutropenie, pansitopenie en leukopenie.
BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
Simptome as gevolg van orfenadrien (anticholinergies) sluit in:
Tagikardie, vinnige of moeilike asemhaling, hiperpireksie, rusteloosheid, verwarring, opgewondenheid en hallusinasies wat oorgaan na delirium. 'n Uitslag op die gesig en boonste borskas kan verskyn. Met ernstige oordosering kan depressie van die sentrale senuweestelsel voorkom, asook hipertensie of sirkulasie versaking en onderdrukking van die respiratories stelsel.
Behandeling: Ledig die maag deur aspirasie en spoeling. 'n Purgeermiddel kan ook toegedien word. Verdere behandeling is simptomaties.
Simptome as gevolg van parasetamol-oordosering:
Simptome as gevolg van parasetamol-oordosering in die eerste 24 uur is bleekheid, braking, anoreksie en maagpyn. Lewerskade kan voorkom 12 tot 48 uur na inname. Abnormaliteite van glukosemetabolisme en metaboliese asidose kan voorkom.
Akute nierversaking en akute tubulêre nekrose kan ontwikkel selfs in die afwesigheid van ernstige lewerskade. Kardiale aritmieë is gerapporteer. Simptome gedurende die eerste 2 dae na akute oordosering reflekteer nie die potensiële ernstigheid van die oordosering nie.
Naarheid, braking, anoreksie en maagpyn kan vir 'n week of meer voortduur. Lewerskade kan voorkom op die tweede dag (of later), aanvanklik deur verhoging van die transaminase en melksuur dehidrogenase aktiwiteit, verhoogde serum bilirubien konsentrasies en verlenging van die protrombien tyd. Die lewerskade kan verder ontwikkel tot ensefalopatie, koma en dood. Serebrale edeem en nie-spesifieke miokardiale depressie kan ook voorkom. Wanneer 'n oordosering plaasvind, raadpleeg 'n geneesheer of neem die pasiënt onmiddelik na die naaste hospitaal.
Gespesialiseerde behandeling is noodsaaklik, so spoedig moontlik. Onmiddelike behandeling is noodsaaklik. Enige pasiënt wat ongeveer 7,5 g parasetamol in die voorafgaande 4 uur ingeneem het behoort maagspoeling te ondergaan. Spesifieke terapie met 'n teenmiddel soos asetielsisteïen of metionien mag nodig wees. Indien sodanig besluit word, behoort die asetielsisteïen intraveneus toegedien word so spoedig moontlik.
Asetielsisteïen: Asetielsisteïen behoort so spoedig moontlik toegedien te word, verkieslik binne 8 uur na oordosering.
Intraveneus: 'n Aanvanklike dosis van 150 mg/kg in 200 mℓ glukose, moet binneaars oor 15 minute toegedien word, gevolg deur 'n binneaarse infusie van 50 mg/kg in 500 mℓ glukose oor die volgende 4 uur, en dan 100 mg/kg in 1 000 mℓ oor die volgende 16 uur. Die volume binneaarse vloeistof moet aangepas word vir kinders.
Per mond: 140 mg/kg van 'n 5 % oplossing, gevolg deur 70 mg/kg oplossing elke 4 uur vir 17 dosisse. Asetielsisteïen is effektief indien dit binne 8 uur na oordosering toegedien word.
IDENTIFIKASIE
Wit gekerfde bikonvekse tablette met N/C aan een kant en geen merke op die ander kant.
AANBIEDING
Stulpverpakking van 24 en 48 tablette. Plastiek bottels met 120 tablette.
BERGINGSAANWYSINGS
Bewaar teen of benede 30 °C in 'n droë plek.
HOU BUITE BEREIK VAN KINDERS.
VERWYSINGSNOMMER
B1098 (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
Julie 1992

314mm

Norflex® Co

SCHEDULING STATUS S2
PROPRIETARY NAME AND DOSAGE FORM
NORFLEX® CO Tablets

COMPOSITION
Each tablet contains 35 mg Orphenadrine citrate and 450 mg Paracetamol. Other excipients include colloidal silicondioxide, magnesium stearate, microcrystalline cellulose, pregelatinised maize starch. SUGAR FREE.
PHARMACOLOGICAL CLASSIFICATION
A 2.9 (Other analgesics)
PHARMACOLOGICAL ACTION
Orphenadrine is an anticholinergic agent. It also has weak antihistaminic, local anaesthetic and skeletal muscle relaxant properties.
Paracetamol has analgesic and antipyretic properties.
INDICATIONS
To relieve pain due to spasm of voluntary muscle and for the symptomatic treatment of mild to moderate pain and/or fever.
CONTRAINDICATIONS
NORFLEX CO should be used with caution in the presence of tachycardia, urinary retention and myasthenia gravis. It is contraindicated in patients with prostatic enlargement and should be used with caution in elderly men. It is also contraindicated in patients suffering from paralytic ileus or pyloric stenosis where its use may lead to obstruction.
It should not be given to patients with closed angle glaucoma or to patients with a narrow angle between the iris and the cornea since it may raise intraocular pressure. The risk is greater in patients over 40 years of age.
It should not be given to patients, especially children when the ambient temperature is high, due to the risk of provoking hyperpyrexia. It should be used cautiously in patients with fever.
It should be used with caution in conditions characterised by tachycardia such as thyrotoxicosis, cardiac insufficiency or failure and in cardiac surgery.
Safe use in pregnancy has not been established; therefore **Norflex Co** should not be used in pregnant women.
Sensitivity to any of the ingredients.
Severe liver function impairment.
WARNINGS
Do not use continuously for more than 10 days without consulting your doctor.
Dosage in excess of those recommended may cause severe liver damage. Patients suffering from liver or kidney disease should take paracetamol under medical supervision.
Consult a doctor if no relief is obtained from the recommended dosage.
DOSAGE AND DIRECTIONS FOR USE
Adults: Two tablets three or four times a day.
SIDE EFFECTS AND SPECIAL PRECAUTIONS
Side effects due to anticholinergic type action:
Dryness of the mouth with difficulty in swallowing, dilation of the pupils, loss of accommodation and photophobia, increased intraocular pressure, flushing and dryness of the skin, transient bradycardia followed by tachycardia, with palpitations and arrhythmias and the desire to urinate with the inability to do so, as well as reduction in the tone and motility of the gastro-intestinal tract leading to constipation. Occasional vomiting, giddiness, and staggering may occur.
Retrosternal pain may occur due to increased gastric reflux. Insomnia has been reported.
Mental confusion, especially in the elderly. Reduced bronchial secretion may be associated with the formation of mucus plugs.
Persons with Down's syndrome appear to have an increased susceptibility, whereas those with albinism may be resistant. The effect of anticholinergic agents may be enhanced by the concomitant administration of other drugs with anticholinergic properties such as amantadine, some antihistamines, butyrophenones and phenothiazines and tricyclic antidepressants.
Orphenadrine has been abused for supposed euphoriant effect.
Side effects due to paracetamol:
Skin rashes and other allergic reactions may occur. The rash is usually erythematous or urticarial, but sometimes more serious and may be accompanied by fever and mucosal lesions.
The use of paracetamol has been associated with the occurance of neutropenia, pancytopenia and leucopenia.
KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Symptoms due to orphenadrine (anticholinergic) include:
Tachycardia, rapid or stertorous respiration, hyperpyrexia, restlessness, confusion, excitement and hallucinations passing into delirium. A rash on the face and upper trunk may appear.
In severe intoxication, depression of the central nervous system may occur with hypertension or circulatory failure and respiratory depression.
Treatment: Empty the stomach by aspiration and lavage. A purgative may also be given. Further treatment is symptomatic.
Symptoms due to paracetamol: Symptoms in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 24 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur.
Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias have been reported.
Symptoms during the first two days of acute poisoning do not reflect the potential seriousness of the overdose.
Nausea, vomiting, anorexia and abdominal pain may persist for a week or more. Liver injury may become manifest on the second day, (or later) initially by elevation of serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentration and prolongation of prothrombin time. The liver damage may progress to encephalopathy, coma and death. Cerebral oedema and nonspecific myocardial depression have also occurred.
In the event of overdose consult your doctor or take the patient to the nearest hospital immediately.
Specialised treatment is essential as soon as possible.
Prompt treatment is essential. Any patient who has ingested about 7,5 g of paracetamol in the preceding 4 hours should undergo gastric lavage. Specific therapy with an antidote such as acetylcysteine or methionine may be necessary. If decided upon, acetylcysteine should be administered IV as soon as possible.
Acetylcysteine: Acetylcysteine should be administered as soon as possible, preferably within 8 hours of overdosage.
IV: An initial dose of 150 mg/kg in 200 mℓ glucose injection, given intravenously over 15 minutes, followed by an intravenous infusion of 50 mg/kg in 500 mℓ of glucose injection over the next 4 hours, and then 100 mg/kg in 1 000 mℓ over the next 16 hours. The volume of intravenous fluids should be modified for children.
Orally: 140 mg/kg as a 5 % solution, followed by a 70 mg/kg solution every 4 hours for 17 doses. Acetylcysteine is effective if administered within 8 hours of overdosage.
IDENTIFICATION
White scored biconvex tablets with N/C on the one side and no markings on the other.
PRESENTATION
Blister packs of 24 and 48 tablets. Plastic bottles of 120 tablets.
STORAGE INSTRUCTIONS
Store at or below 30 °C in a dry place.
KEEP OUT OF REACH OF CHILDREN.
REFERENCE NUMBER
B1098 (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
July 1992

NAMIBIA	**ZIMBABWE** - Category of distribution:	**BOTSWANA**
Scheduling Status: NS1	Pharmacist Initiated Medicine (PIM)	Scheduling status: 2
Registration Number: 14/5.8/0282	Registration Number: 77/2.2/837	Registration number : B9308700

LT061.062.063.01.18 LT0114

314mm