SCHEDULING STATUS: S1

PROPRIETARY NAME AND DOSAGE FORM:

JACK'S THICK NOSE DROPS

COMPOSITION: Each 10 mL contains:
Phenylephrine hydrochloride 25 mg
Naphazoline nitrate 2,5 mg
Inactive ingredients: Carmellose sodium, sodium chloride and water.
Preservatives: Chlorbutol 0,15 % *m/v*, sodium methyl hydroxybenzoate 0,10 % *m/v*.
CATEGORY AND CLASS: A 16.1 Nasal decongestants.
PHARMACOLOGICAL ACTION: Nasal decongestants.
INDICATIONS: For prompt and complete relief of nasal congestion in colds, catarrh, sinusitis and hay fever.
CONTRAINDICATIONS: Not to be used by children under 2 years of age.
WARNINGS AND SPECIAL PRECAUTIONS: FOR NASAL USE ONLY.
INTERACTIONS: None known.
HUMAN REPRODUCTION: Safety and efficacy during pregnancy and lactation have not been established.
DOSAGE AND DIRECTIONS FOR USE: Adults: 3 – 4 drops in each nostril.
Children older than 2 years: 1 – 2 drops in each nostril.
Use every four hours if necessary.
Not to be used for babies.
SIDE EFFECTS: Undesirable high blood pressure may occur with headache, vomiting and rarely palpitations. Reflex bradycardia may occur which can be prevented or abolished with atropine.
Use with caution in patients with hypertension, hyperthyroidism, aneurysm, arteriosclerosis and cardiovascular disorders.
Excessive use can lead to rebound congestion.
Should not be given to patients being treated with monoamine oxidase inhibitors, or within 14 days of stopping such treatment. It should be avoided in patients receiving tricyclic antidepressants.
KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Accidental administration by mouth causes depression of the central nervous system, with symptoms of drowsiness, reduction in body temperature and coma. Treat symptomatically.
IDENTIFICATION: Thick clear liquid.
PRESENTATION: 30 mL round amber glass dropper bottle with black screw cap, fitted with black rubber teat and clear glass pipette.
STORAGE INSTRUCTIONS: Store at or below 25 °C. Protect from light.
Keep well closed until required for use.
KEEP OUT OF REACH OF CHILDREN.
REFERENCE NUMBER: H1451 (ACT 101/1965)
NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
LeBasi Pharmaceuticals (Pty) Ltd
San Domenico Building, Unit 6, 10 Church Street, Durbanville 7551.
087 551 3245 www.lebasi.co.za
Marketed by:
Brunel Laboratoria (Pty) Ltd
1 Van Tonder Street, Sunderland Ridge, Centurion 0157.
info@brunel.co.za
DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:
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Date of revision: 25 September 2018

SKEDULERINGSTATUS: S1

HANDELSNAAM EN DOSEERVORM:

JACK'S THICK NOSE DROPS (druppels)

SAMESTELLING: Elke 10 mL bevat:
Fenielefrienhidrochloried 25 mg
Nafasoliennitraat 2,5 mg
Onaktiewe bestanddele: Natriumkarmellose, natriumchloried en water.
Preserveermiddels: Chloorbutol 0,15 % *m/v*, natriummetielhidroksibensoaat 0,10 % *m/v*.
KATEGORIE EN KLAS: A 16.1 Nasale ontstuwingsmiddels.
FARMAKOLOGIESE WERKING: Nasale ontstuwingsmiddels.
INDIKASIES: Vir vinnige en volkome verligting van 'n toe neus weens verkoue, katar, sinusitis en hooikoors.
KONTRA-INDIKASIES: Moenie deur kinders jonger as 2 jaar gebruik word nie.
WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS: SLEGS VIR NASALE GEBRUIK.
INTERAKSIES: Daar is geen interaksies bekend nie.
MENSLIKE VOORTPLANTING: Veiligheid en effektiwiteit tydens swangerskap en borsvoeding is nie vasgestel nie.
DOSIS EN GEBRUIKSAANWYSINGS: Volwassenes: 3 – 4 druppels in elke neusgang.
Kinders ouer as 2 jaar: 1 – 2 druppels in elke neusgang.
Gebruik elke vier uur, indien nodig.
Moenie vir babas gebruik word nie.
NEWE-EFFEKTE: Ongewenste hoë bloeddruk kan voorkom met gepaardgaande hoofpyn, braking en by uitsondering hartkloppings. Refleks bradikardie mag ontwikkel, wat met atropien verhoed of uitgeskakel kan word. Gebruik versigtig by pasiënte met hoë bloeddruk, hipertiroïdisme, aneurisme, arteriosklerose en kardiovaskulêre versteurings.
Oormatige gebruik kan herhalende kongestie veroorsaak.
Dit moenie aan pasiënte gegee word wat met 'n monoamienoksidase-inhibeerder behandel word, of binne 14 dae nadat sodanige behandeling gestaak is nie. Gebruik moet vermy word by pasiënte wat trisikliese antidepressante ontvang.
BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN: Toevallige inname per mond veroorsaak onderdrukking van die sentrale senuweestelsel, met simptome van lomerigheid, verlaging van liggaamstemperatuur en koma. Behandel die simptome.
IDENTIFIKASIE: Dik, helder vloeistof.
AANBIEDING: 30 mL ronde amber glas drupbottel met 'n swart skroefprop, 'n swart rubberspeen en deurskynende glas pipet.
BERGINGSINSTRUKSIES: Bêre by of onder 25 °C. Beskerm teen lig.
Hou dig toe tot nodig vir gebruik.
HOU BUITE BEREIK VAN KINDERS.
VERWYSINGSNOMMER: H1451 (WET 101/1965)
NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
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