Pholtex® PLUS

Package insert

SCHEDULING STATUS S2
PROPRIETARY NAME AND DOSAGE FORM
PHOLTEX PLUS, liquid.

COMPOSITION
Each 5 mℓ contains:
Pholcodine 5 mg
Phenylephrine hydrochloride 3,3 mg
Preservatives:
Methylhydroxybenzoate 0,1 % *m/v*
Propylhydroxybenzoate 0,02 % *m/v*
Inactive ingredients include citric acid anhydrous, custard flavour, glycerol, hydroxymethylcellulose, purified water, raspberry flavour.
Contains sugar: sorbitol solution 1,75 g/5 mℓ
Contains sweetener: saccharin sodium 1,5 mg/5 mℓ
Contains amaranth (colour) CI 16185
PHARMACOLOGICAL CLASSIFICATION
A.16.5 Others
PHARMACOLOGICAL ACTION
Pharmacodynamic properties
Pholcodine is a cough suppressant. It is centrally acting with a direct action on the cough centre in the medulla.
Phenylephrine hydrochloride is a sympathomimetic medicine with mainly direct effects on adrenergic receptors. It has predominantly alpha adrenergic activity and is without significant stimulating effects on the central nervous system at usual dose. Its pressor activity is weaker than that of ephedrine.
Pharmacokinetic properties
Phenylephrine hydrochloride has low oral bioavailability owing to irregular absorption and first-pass metabolism by monoamine oxidase in the gut and liver.
INDICATIONS
PHOLTEX PLUS provides relief of dry coughs and nasal congestion.
CONTRAINDICATIONS
Hypersensitivity to pholcodine and phenylephrine hydrochloride or to any of the ingredients of **PHOLTEX PLUS**.
Children under two years of age.
Patients taking monoamine oxidase inhibitors or within 14 days of stopping such medicines (see **INTERACTIONS**).
PHOLTEX PLUS should not be given to patients with:
- diabetes mellitus
- prostatic hyperplasia
- chronic bronchitis; chronic obstructive pulmonary disease; bronchiolitis or bronchiectasis due to sputum retention
- hyperthyroidism as phenylephrine hydrochloride induces tachycardia or reflex bradycardia (See **WARNINGS AND SPECIAL PRECAUTIONS**)
- the risk of developing respiratory failure (may depress respiration) and patients with renal or hepatic failure.

PHOLTEX PLUS is contraindicated in pregnancy and lactation. (See **PREGNANCY AND LACTATION**).
WARNINGS AND SPECIAL PRECAUTIONS
Use of pholcodine as in **PHOLTEX PLUS** with alcohol or other CNS depressants may increase the effects on the CNS and cause toxicity in relatively smaller doses.
PHOLTEX PLUS should be used with caution in elderly patients or in patients with uncontrolled hypertension, advanced arteriosclerosis and glaucoma.
Phenylephrine hydrochloride in **PHOLTEX PLUS** may increase the cardiac effect with medicines that increase the sensitivity of the myocardium to beta1-agonists and may cause hazardous dysrhythmias with volatile anaesthetics. Caution is also required with thyroid hormones and medicines that affect cardiac conduction such as digoxin and antidysrhythmic medicines.
Beta-blockers should be used with caution since it may increase the risk of hypertension and reflex bradycardia. (See **CONTRAINDICATIONS**.)
Alpha-blockers should be used with caution since it may increase the risk of hypotension and tachycardia.
Effects on ability to drive and use machines:
PHOLTEX PLUS may cause dizziness and drowsiness in some people. Caution should be exercised when driving or operating machines. (See **SIDE EFFECTS**).
Excipients
PHOLTEX PLUS contains sorbitol solution which may have a laxative effect. Patients with the rare hereditary condition of sorbitol intolerance should not take **PHOLTEX PLUS**.
INTERACTIONS
PHOLTEX PLUS should not be taken with the following:
- alcohol – this may increase the effect on the central nervous system
- central nervous system depressants – this may increase the effect on the central nervous system
- monoamine oxidase inhibitors, if used within the last 14 days – a hypertensive crisis may occur. (See **CONTRAINDICATIONS**).
- tricyclic antidepressants – this may block the inactivation of epinephrine (adrenaline) and norepinephrine (noradrenaline) by uptake into the nerve endings and may increase the effect of phenylephrine hydrochloride
- central nervous system stimulants – phenylephrine hydrochloride may potentiate the effects of central nervous system stimulants, while the vasoconstrictor and pressor effects of alpha agonists such as ergot alkaloids or oxytocin, may be enhanced.
- antihypertensive medicines – reversal of the action of antihypertensive medicines may occur
- neuromuscular blocking medicines – interactions with alpha- and beta-blockers can cause a hypertensive crisis.

PREGNANCY AND LACTATION
PHOLTEX PLUS is contraindicated in pregnancy and lactation.
In pregnancy, phenylephrine hydrochloride may promote uterine contractibility and peripheral vasoconstriction.
DOSAGE AND DIRECTIONS FOR USE
Adults and children over 12 years:
10 – 15 mℓ (two to three medicine measures) every 6 hours.
Children 6 – 12 years:
5 – 10 mℓ (one to two medicine measures) every six hours.
Children under six years:
Not indicated.
PHOLTEX PLUS is contraindicated in children less than two years. The maximum dose is every six hours (four times a day).
SIDE EFFECTS
The following side effects may occur when taking **PHOLTEX PLUS**:
Metabolism and nutrition disorders:
Frequency unknown:
Hyperglycaemia, hypokalaemia, lactic acidosis.
Psychiatric disorders:
Frequency unknown:
Psychotic states, anorexia insomnia.
Nervous system disorders:
Frequency unknown:
Headache, drowsiness, restlessness, excitement, ataxia, fear, anxiety, irritability, confusion, weakness, fainting, dizziness, tremor, piloerection, sweating.
Eye disorders:
Frequency unknown:
Mydriasis.
Cardiac disorders:
Frequency unknown:
Tachycardia, bradycardia, cardiac dysrhythmias, palpitations.
Vascular disorders:
Frequency unknown:
Flushing.
Respiratory, thoracic and mediastinal disorders:
Frequency unknown:
Respiratory depression, dyspnoea.
Gastrointestinal disorders:
Frequency unknown:
Nausea, vomiting, constipation.
Skin and subcutaneous tissue disorders:
Frequency unknown:
Rash, itching, hives and facial oedema.
Renal and urinary disorders:
Frequency unknown:
Difficulty in micturition, urinary retention.
KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
In the event of overdosage, emergency treatment should be started immediately.
Symptoms include drowsiness, restlessness, excitement, ataxia and respiratory depression.
Severe increase in blood pressure may occur.
Treatment:
There is no specific antidote and treatment is symptomatic and supportive.
Treatment with alpha-adrenergic blocking medicines to reduce blood pressure should be instituted if myocardial ischaemia is provoked.
IDENTIFICATION
PHOLTEX PLUS is a clear red, slightly viscous liquid with the odour of raspberry and custard.
PRESENTATION
100 mℓ and 200 mℓ amber polyethylene terephthalate bottles with a 28 mm polypropylene tamper evident cap in a printed carton.
STORAGE INSTRUCTIONS
Store at or below 30 °C in a cool, dry place. Keep well closed. Do not refrigerate. Shake bottle before use. KEEP OUT OF REACH OF CHILDREN.
REGISTRATION NUMBER
46/16.5/0711
NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
iNova Pharmaceuticals (Pty) Ltd
15E Riley Road, Bedfordview, Gauteng, 2007
DATE OF PUBLICATION OF THE PACKAGE INSERT
27 July 2017

LT101.102.08.17

Pholtex® PLUS

Patient Information Leaflet

SCHEDULING STATUS S2
PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
PHOLTEX PLUS, pholcodine 5 mg/5 mℓ, phenylephrine hydrochloride 3,33 mg/5 mℓ, liquid.

Read all of this leaflet carefully because it contains important information for you
PHOLTEX PLUS is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use **PHOLTEX PLUS** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **PHOLTEX PLUS** with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

WHAT PHOLTEX PLUS CONTAINS
The active ingredients are:
Pholcodine 5 mg
Phenylephrine hydrochloride 3,3 mg
Preservatives:
Methylhydroxybenzoate 0,1 % *m/v*
Propylhydroxybenzoate 0,02 % *m/v*
The other ingredients are citric acid anhydrous, custard flavour, glycerol, hydroxymethylcellulose, purified water, raspberry flavour.
PHOLTEX PLUS contains sugar (sorbitol solution 1,75 g/5 mℓ), contains sweetener (saccharin sodium 1,5 mg/5 mℓ), contains amaranth (Colour) CI 16185.
WHAT PHOLTEX PLUS IS USED FOR
PHOLTEX PLUS is used to provide relief of dry coughs and nasal congestion.
BEFORE YOU TAKE PHOLTEX PLUS
Do not take PHOLTEX PLUS:
- if you are hypersensitive (allergic) to pholcodine, phenylephrine hydrochloride or any of the other ingredients of **PHOLTEX PLUS**
- if you are under 2 years of age
- if you have diabetes mellitus
- if you have an enlarged prostate
- if you have an overactive thyroid which may either increase your heartbeat or decrease your heartbeat
- if you are pregnant or breastfeeding
- if you use antidepressants called monoamine oxidase inhibitors or within 14 days of stopping such medicines
- if you have chronic bronchitis, lung disease (obstructive pulmonary disease), inflammation of the smaller air passages of the lungs (bronchiolitis) or if your airways are enlarged due to retention of saliva
- if you are at risk of developing respiratory failure (difficulty breathing) or if your liver and kidneys are not functioning properly.

Take special care with PHOLTEX PLUS:
- do not take alcohol or other medicines called central nervous system depressants with **PHOLTEX PLUS**, since this may increase the effects on the central nervous system and cause toxicity
- if you are elderly
- if you suffer from high blood pressure
- if you have arteriosclerosis (thickening or hardening of the arteries)
- if you have glaucoma (increased pressure in your eye)
- if you use medicine for your heart, such as digoxin or medicines to maintain a regular heartbeat
- if you use medicine for your thyroid gland
- if you are getting inhalation anaesthetics
- if you use medicines called Alpha- and Beta-blockers.

Pregnancy and Breastfeeding:
PHOLTEX PLUS should not be used during pregnancy.
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **PHOLTEX PLUS.**
Driving and using machinery:
- **PHOLTEX PLUS** may make you feel dizzy and sleepy
- be careful when driving or operating machines.

Important information about some of the ingredients of PHOLTEX PLUS:
- **PHOLTEX PLUS** contains sorbitol solution which may have a laxative effect
- if you have the rare hereditary condition of sorbitol intolerance, you should not take P**HOLTEX PLUS**.

Taking other medicines with PHOLTEX PLUS:
Always tell your healthcare professional if you are taking any other medicines (This includes complementary or traditional medicines.)
- do not take alcohol or other central nervous system depressants together with **PHOLTEX PLUS** since it may increase the effect on the central nervous system
- do not take **PHOLTEX PLUS** if you are using or were using monoamine oxidase inhibitors (a medicine used for depression) in the last 14 days. It may increase your blood pressure
- do not take tricyclic antidepressants with **PHOLTEX PLUS** - this may increase the effect of phenylephrine hydrochloride
- do not take **PHOLTEX PLUS** together with central nervous system stimulants – phenylephrine hydrochloride may increase the effect of the central nervous system stimulants and the effects of medicines called alpha agonists
- do not take **PHOLTEX PLUS** if you are using medicines for high blood pressure – this may reverse the effect of your blood pressure medicine
- do not take **PHOLTEX PLUS** if you use medicines called neuromuscular blockers – this might cause your blood pressure to severely increase.

HOW TO USE PHOLTEX PLUS
Do not share medicines prescribed for you with any other person.
Always take **PHOLTEX PLUS** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
The usual dose is:
Adults and children over 12 years:
10 – 15 mℓ (two to three medicine measures) every 6 hours.
Children 6 – 12 years:
5 – 10 mℓ (one to two medicine measures) every 6 hours.
Children under 6 years:
Not to be used. **PHOLTEX PLUS** is contraindicated in children under two years old.
The maximum dose is every 6 hours (four times a day)
If you take more PHOLTEX PLUS than you should:
Go to your nearest hospital.
You might experience the following:
- feel sleepy
- feel restless
- feel excited
- have difficulty moving
- have difficulty breathing
- feel a severe increase in blood pressure.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.
If you forget to take PHOLTEX PLUS:
Do not take a double dose to make up for forgotten individual doses.
POSSIBLE SIDE EFFECTS
PHOLTEX PLUS can have side effects.
Not all side effects reported for **PHOLTEX PLUS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **PHOLTEX PLUS**, please consult your doctor, pharmacist or other healthcare professional for advice.
If any of the following happens, stop taking **PHOLTEX PLUS** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- if you have difficulty breathing
- if you have an irregular heartbeat (fast or slow heartbeat or heart palpitations)
- if you have a rash or start itching or get hives
- if your face, lips, tongue or other parts of the body starts swelling.

These are all very serious side effects. If you have them, you might have had a serious allergic reaction to **PHOLTEX PLUS**. You may need urgent medical attention or hospitalisation.
Tell your doctor as soon as possible if you notice any of the following:
- if your blood sugar increases (you might get headaches, blurred vision, or frequent urination)
- if you get anorexia
- if you have a headache
- if you feel sleepy or restless
- if you feel excited
- if you feel that you do not have control of your body
- if you feel afraid, anxious or irritable
- if you feel confused
- if you feel weak, dizzy or tremble
- if you faint
- if you have difficulty sleeping
- if you are sweating excessively or feel flushed
- if you get an involuntary erection
- if your pupils are dilated
- if you are nauseas or vomit
- if you are constipated
- if you have difficulty urinating.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.
STORING AND DISPOSING OF PHOLTEX PLUS
Store all medicines out of reach of children.
Store at or below 30 °C in a cool dry place. Keep well closed. Do not refrigerate. Shake bottle before use. Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
PRESENTATION OF PHOLTEX PLUS
PHOLTEX PLUS is packed in 100 mℓ or 200 mℓ amber plastic bottles with a plastic cap, packed in a printed cardboard box.
IDENTIFICATION OF PHOLTEX PLUS
PHOLTEX PLUS is a clear red, slightly viscous liquid with the odour of raspberry and custard.
REGISTRATION NUMBER
46/16.5/0711
NAME AND ADDRESS OF REGISTRATION HOLDER
iNova Pharmaceuticals (Pty) Ltd
15E Riley Road, Bedfordview, Gauteng, 2007
DATE OF PUBLICATION
27 July 2017

Pholtex® PLUS

Voubiljet

SKEDULERINGSTATUS S2

EIENDOMSNAAM EN DOSEERVORM
PHOLTEX PLUS, vloeistof.

SAMESTELLING
Elke 5 mℓ bevat:
Folkodien 5 mg
Fenielefrienhidrochloried 3,3 mg
Preserveermiddels:
Metielhidroksibensoaat 0,1 % *m/v*
Propielhidroksibensoaat 0,02 % *m/v*
Onaktiewe bestanddele sluit watervrye sitroensuur, vlageursel, gliserol, hidroksimetielsellulose, gesuiwerde water en framboosgeursel in.
Bevat suiker: sorbitoloplossing 1,75 g/5 mℓ
Bevat versoeter: natriumsakkarien 1,5 mg/5 mℓ
Bevat amarant (kleur) CI 16185

FARMAKOLOGIESE KLASSIFIKASIE
A.16.5 Ander

FARMAKOLOGIESE WERKING
Farmakodinamiese eienskappe
Folkodien is 'n hoesonderdrukker. Dit is sentraalwerkend met 'n direkte effek op die hoessentrum in die medulla.
Fenielefrienhidrochloried is 'n simpatomimetiese middel met hoofsaaklik direkte effekte op adrenerge reseptore. Dit het oorwegend alfa-adrenergiese aktiwiteit en het by die normale dosis geen beduidende stimulerende effekte op die sentrale senuweestelsel nie. Die pressoraktiwiteit is swakker as dié van efedrien.
Farmakokinetiese eienskappe
Fenielefrienhidrochloried het lae orale biobeskikbaarheid as gevolg van onreëlmatige absorpsie en eerstedeurgangmetabolisme deur monoamienoksidase in die ingewande en lewer.

INDIKASIES
PHOLTEX PLUS bied verligting van droë hoes en neuskongestie.

KONTRA-INDIKASIES
Hipersensitiwiteit teenoor folkodien of fenielefrienhidrochloried of enige van die bestanddele van **PHOLTEX PLUS**.
Kinders jonger as twee jaar.
Pasiënte wat monoamienoksidaseinhibeerders gebruik of binne 14 dae na staking daarvan (Sien **INTERAKSIES**).
PHOLTEX PLUS moet nie aan pasiënte gegee word met:
- diabetes mellitus
- prostaathiperplasie
- chroniese brongitis; chroniese obstruktiewe pulmonêre siekte; brongiolitis of brongiëktase as gevolg van sputumretensie
- hipertiroïdisme, aangesien fenielefrienhidrochloried tagikardie of refleksbradikardie induseer (sien **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS**)
- risiko om respiratoriese ineenstorting te ontwikkel (kan respirasie onderdruk), asook pasiënte met nier- of lewerversaking.

PHOLTEX PLUS is teenaangedui tydens swangerskap en borsvoeding (sien **SWANGERSKAP EN BORSVOEDING**).

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS
Gebruik van folkodien soos in **PHOLTEX PLUS** saam met alkohol of ander onderdrukkers van die SSS kan die effekte op die SSS versterk en toksisiteit veroorsaak teen relatief laer dosisse.
PHOLTEX PLUS moet versigtig gebruik word deur bejaarde pasiënte of pasiënte met ongekontrolleerde hipertensie, gevorderde arteriosklerose of gloukoom.
Fenielefrienhidrochloried in **PHOLTEX PLUS** kan die kardiale effek versterk saam met middels wat die sensitiwiteit van die miokardium teenoor beta1-agoniste verhoog, en kan saam met vlugtige anestetika gevaarlike disritmie veroorsaak. Wees ook versigtig met skildklierhormone en medisyne wat hartgeleiding beïnvloed, soos digoksien- en antidisritmiese middels.
Beta-blokkers moet versigtig gebruik word, aangesien dit die risiko vir hipertensie en refleksbradikardie kan verhoog (sien **KONTRA-INDIKASIES**).
Alfa-blokkers moet versigtig gebruik word, aangesien dit die risiko vir hipotensie en tagikardie kan verhoog.
Effekte op vermoë om te bestuur en masjinerie te gebruik:
PHOLTEX PLUS kan duiseligheid en lomerigheid in sommige mense veroorsaak. Wees versigtig wanneer 'n voertuig bestuur of swaar masjinerie hanteer word. (Sien **NEWE-EFFEKTE**.)
Hulpstowwe
PHOLTEX PLUS bevat sorbitoloplossing wat 'n lakserende effek kan hê. Pasiënte met die skaars oorerflike toestand van sorbitol onverdraagbaarheid moet nie **PHOLTEX PLUS** gebruik nie.

INTERAKSIES
PHOLTEX PLUS moet nie saam met die volgende gebruik word nie:
- alkohol - dit kan die effek op die sentrale senustelsel versterk
- sentrale senustelsel (SSS)-onderdrukkers - dit kan die effek op die sentrale senustelsel versterk
- monoamienoksidaseremmers, wanneeer gebruik in die voorafgaande 14 dae – dit mag 'n hipertensiewe krisis tot gevolg hê (sien **KONTRA-INDIKASIES**)
- trisikliese antidepressante - dit kan die inaktivering van epinefrien (adrenalien) en norepinefrien (noradrenalien) deur middel van opname in die senuwee-eindpunte blokkeer en kan die effek van fenielefrienhidrochloried versterk
- sentrale senustelsel (SSS)-stimulante - fenielefrienhidrochloried kan die effekte van sentrale senustelsel stimulante versterk, terwyl die vasokonstriktor- en pressoreffekte van alfa-agoniste, soos ergotalkaloïede of oksitosien, versterk kan word
- antihipertensiewe middels - omkering van die werking van antihipertensiewe middels kan voorkom
- neuromuskulêre blokkers - interaksies met alfa- en beta-blokkers kan 'n hipertensiewe krisis veroorsaak.

SWANGERSKAP EN BORSVOEDING
PHOLTEX PLUS is teenaangedui tydens swangerskap en borsvoeding
Tydens swangerskap kan fenielefrienhidrochloried kontraktiliteit van die baarmoeder en perifere vasokonstriksie bevorder.

DOSIS EN GEBRUIKSAANWYSINGS
Volwassenes en kinders ouer as 12 jaar:
10 - 15 mℓ (twee tot drie medisynemate) elke 6 uur.
Kinders 6 - 12 jaar:
5 - 10 mℓ (een tot twee medisynemate) elke 6 uur.
Kinders jonger as ses jaar:
Nie aangedui nie.
PHOLTEX PLUS is teenaangedui vir kinders jonger as twee jaar. Die maksimum dosis is elke ses uur (vier maal per dag).

NEWE-EFFEKTE
Die volgende newe-effekte kan voorkom wanneer **PHOLTEX PLUS** gebruik word:
Metaboliese en voedingsiektes:
Minder algemeen:
Hiperglukemie, hipokalemie, melksuurasidose.
Psigiatriese siektes:
Minder algemeen:
Psigotiese toestande, anoreksie, slapeloosheid.
Senustelsel siektes:
Minder algemeen:
Hoofpyn, lomerigheid, rusteloosheid, opgewondenheid, ataksie, vrees, angs, prikkelbaarheid, verwardheid, swakheid, floute, duiseligheid, bewing, piloëreksie, sweet.
Oogsiektes:
Minder algemeen:
Midriase.
Hartsiektes:
Minder algemeen:
Tagikardie, bradikardie, hartdisritmie, hartkloppings.
Vaskulêre siektes:
Minder algemeen:
Blosing.
Respiratoriese, toragiese en mediastinale siektes:
Minder algemeen:
Asemhalingsonderdrukking, dispnee.
Gastro-intestinale siektes:
Minder algemeen:
Naarheid, braking, hardlywigheid.
Vel- en subkutane weefsel siektes:
Minder algemeen:
Veluitslag, jeuk, galbulte en gesigsedeem.
Nier- en urinêre siektes:
Minder algemeen:
Moeilike urinering, urienretensie.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN
In geval van oordosering moet noodbehandeling dadelik gegee word.
Simptome sluit lomerigheid, rusteloosheid, opgewondenheid, ataksie en respiratoriese onderdrukking in. Erge toename in bloeddruk kan voorkom.
Behandeling:
Daar is geen spesifieke teenmiddel beskikbaar nie en behandeling is simptomaties en ondersteunend. Behandeling met alfa-adrenerge blokkers om bloeddruk te verlaag, moet ingestel word indien miokardiale iskemie ontlok is.

IDENTIFIKASIE
PHOLTEX PLUS is 'n helder rooi, effens viskose vloeistof met die reuk van framboos en vla.

AANBIEDING
100 mℓ en 200 mℓ bruin poliëtileentereftalaatbottels met 28 mm peutervrye polipropileenproppe in 'n gedrukte karton.

BEWARINGSINSTRUKSIES
Bewaar teen of benede 30 °C in 'n koel, droë plek. Hou styf toegedraai. Moenie in die yskas bêre nie. Skud bottel voor gebruik. HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER
46/16.5/0711

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

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET
27 Julie 2017

Pholtex® PLUS

Pasiëntinligtingsblad
SKEDULERINGSTATUS S2
EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM
PHOLTEX PLUS, folkodien 5 mg/5 mℓ, fenielefrienhidrochloried 3,33 mg/5 mℓ, vloeistof.

Lees hierdie hele voubiljet noukeurig deur omdat dit belangrike inligting vir u bevat.
PHOLTEX PLUS is beskikbaar aan u sonder 'n dokter se voorskrif om 'n matige siekte te behandel.
U moet **PHOLTEX PLUS** nogtans versigtig gebruik om die beste resultate daaruit te verkry.
- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- Moenie **PHOLTEX PLUS** met enigiemand anders deel nie.
- Raadpleeg u apteker indien u nog inligting of raad nodig het.
- U moet 'n dokter konsulteer as u simptome vererger of nie verbeter nie.

WAT PHOLTEX PLUSPLUS BEVAT
Die aktiewe bestanddele is:
Folkodien 5 mg
Fenielefrienhidrochloried 3,3 mg
Preserveermiddels:
Metielhidroksibensoaat 0,1 % *m/v*
Propielhidroksibensoaat 0,02 % *m/v*
Die ander bestanddele bestaan uit watervrye sitroensuur, vlageursel, gliserol, hidroksimetielsellulose, gesuiwerde water, framboosgeursel.
PHOLTEX PLUS bevat suiker (sorbitoloplossing 1,75 g/5 mℓ), bevat versoeter (natrium-sakkarien 1,5 mg/5 mℓ), bevat amarant (kleur) CI 16185

WAARVOOR PHOLTEX PLUS GEBRUIK WORD
PHOLTEX PLUS word gebruik vir verligting van droë hoes en toe neus.

VOORDAT U PHOLTEX PLUS NEEM
Moenie PHOLTEX PLUS neem:
- as u hipersensitief (allergies) is teenoor folkodien, fenielefrienhidrochloried of enige van die ander bestanddele van **PHOLTEX PLUS**
- as u kind jonger as 2 jaar is
- as u diabetes mellitus het
- as u 'n vergrote prostaat het
- as u 'n ooraktiewe skildklier het wat u hartklop kan versnel of u hartklop kan vertraag
- as u swanger is of borsvoed
- as u antidepressante genaamd monoamienoksidaseremmers gebruik of binne 14 dae na die staking van sulke middels
- as u chroniese brongitis, longsiekte (obstruktiewe pulmonêre siekte), inflammasie van die kleiner lugweë van die longe (bronchiolitis) het, of as u lugweë vergroot is as gevolg van retensie van speeksel
- as u 'n risiko vir die ontwikkeling van respiratoriese versaking (asemhalingsprobleme) het of indien u lewer of niere nie behoorlik werk nie.

Wees besonder versigtig met PHOLTEX PLUS:
- moenie alkohol of ander medisyne genaamd sentrale senustelsel onderdrukkers saam met **PHOLTEX PLUS** gebruik nie, aangesien dit die effekte op die sentrale senustelsel kan versterk en toksisiteit kan veroorsaak
- as u bejaard is
- as u hoë bloeddruk het
- as u arteriosklerose het (verdikking of verharding van die are)
- as u gloukoom het (hoë druk in die oog)
- as u medisyne vir u hart gebruik, byvoorbeeld digoksien, of medisyne om 'n reëlmatige hartklop te handhaaf
- as u medisyne vir u skildklier gebruik
- as u ingasemingsmiddels vir narkose kry
- as u medisyne gebruik wat Alfa- of Beta-blokkers genoem word.

Swangerskap en borsvoeding:
PHOLTEX PLUS moet nie tydens swangerskap gebruik word nie.
As u swanger is of u baba borsvoed, moet u asseblief u dokter, apteker of ander gesondheidskundige om advies raadpleeg voordat u **PHOLTEX PLUS** gebruik.

Motorbestuur en gebruik van masjinerie:
- **PHOLTEX PLUS** kan u duiselig en lomerig laat voel
- wees versigtig as 'n voertuig bestuur of masjinerie hanteer word.

Belangrike inligting oor sommige van die bestanddele van PHOLTEX PLUS:
- **PHOLTEX PLUS** bevat sorbitoloplossing wat 'n lakserende effek kan hê.
- as u die skaars oorerflike toestand van sorbitol onverdraagbaarheid het, moet u nie **PHOLTEX PLUS** neem nie.

Gebruik van ander medisyne saam met PHOLTEX PLUS:
Stel altyd u gesondheidskundige in kennis indien u enige ander medisyne gebruik (dit sluit komplimentêre en tradisionele medisyne in).
- moenie alkohol of ander medisyne wat sentrale senustelsel onderdrukkers genoem word saam met **PHOLTEX PLUS** gebruik nie, aangesien dit die effekte op die sentrale senustelsel kan versterk en toksisiteit kan veroorsaak
- moenie **PHOLTEX PLUS** neem as u monoamienoksidaseremmers gebruik of in die afgelope 14 dae gebruik het nie (medisyne wat vir depressie gebruik word). Dit kan u bloeddruk verhoog
- moenie trisikliese antidepressante saam met **PHOLTEX PLUS** gebruik nie - dit kan die effek van fenielefrienhidrochloried verhoog
- moenie **PHOLTEX PLUS** saam met sentrale senustelsel stimulante gebruik nie - fenielefrienhidrochloried kan die effek van die sentrale senustelsel stimulante versterk asook die effekte van medisyne wat Alfa-agoniste genoem word
- moenie **PHOLTEX PLUS** neem as u medisyne vir hoë bloeddruk gebruik nie - dit kan die effek van u bloeddrukmedisyne omkeer
- moenie **PHOLTEX PLUS** neem as u medisyne gebruik wat neuromuskulêre blokkers genoem word nie. Dit kan veroorsaak dat u bloeddruk ernstig styg.

HOE OM PHOLTEX PLUS TE GEBRUIK
Moenie medisyne wat vir u voorgeskryf met enigiemand anders deel nie.
Gebruik **PHOLTEX PLUS** altyd presies soos wat u dokter aan u verduidelik het. Raadpleeg u dokter of apteker indien u nie seker is nie.
Die algemene dosis is:
Volwassenes en kinders ouer as 12 jaar:
10 - 15 mℓ (twee tot drie medisynemate) elke 6 uur.
Kinders 6 - 12 jaar:
5 - 10 mℓ (een tot twee medisynemate) elke 6 uur.
Kinders jonger as 6 jaar:
Moenie gebruik nie. **PHOLTEX PLUS** is teenaangedui vir kinders jonger as twee jaar.
Die maksimum dosis is elke 6 uur (vier maal per dag).
As u meer PHOLTEX PLUS geneem het as wat u moes:
Gaan na u naaste hospitaal.
U kan dalk die volgende ondervind:
- voel lomerig
- voel rusteloos
- voel opgewek
- moeilike beweging
- moeilike asemhaling
- 'n ernstige styging in bloeddruk.

Raadpleeg u dokter of apteker in geval van oordosering. Indien beide u dokter en apteker nie beskikbaar is nie, kontak die naaste hospitaal of vergiftigingsentrum.
As u vergeet om PHOLTEX PLUS te neem:
Moet nie 'n dubbele dosis gebruik om vir die oorgeslane dosisse op te maak nie.

MOONTLIKE NEWE-EFFEKTE
PHOLTEX PLUS kan newe-effekte veroorsaak.
Nie alle newe-effekte wat vir **PHOLTEX PLUS** aangemeld is, is in hierdie blad opgeneem nie. As u algemene gesondheidstoestand vererger of u ongewenste newe-effekte ervaar terwyl u **PHOLTEX PLUS** gebruik, raadpleeg asseblief u dokter, apteker of ander gesondheidskundige om advies.
Indien enige van die volgende voorkom, moet u ophou om **PHOLTEX PLUS** te gebruik en onmiddellik u dokter raadpleeg of na die ongevalle-afdeling van u naaste hospitaal gaan:
- as u probleme met asemhaling het
- as u 'n onreëlmatige hartklop het (vinnige of stadige hartklop of hartkloppings)
- as u 'n uitslag het of begin jeuk of galbulte kry
- as u gesig, lippe, tong of ander dele van die liggaam begin swel

Hierdie is almal baie ernstige newe-effekte. As u dit ervaar, kan dit wees dat u 'n ernstige allergiese reaksie teenoor **PHOLTEX PLUS** het. U mag dringende mediese aandag of hospitalisasie nodig hê.
Sê so gou as moontlik vir u dokter indien u enige van die volgende opmerk:
- as u bloedsuikervlak styg (u kan hoofpyn, dowwe visie of aanhoudende urinering ervaar)
- as u anoreksie kry
- as u hoofpyn het
- as u lomerig of rusteloos voel
- as u opgewonde voel
- as u voel dat u nie beheer oor u liggaam het nie
- as u bang, angstig of prikkelbaar voel
- as u verward voel
- as u swak of duiselig voel of bewe
- as u flou word
- as u probleme het om te slaap
- as u oormatig sweef of gloede kry
- as u 'n onwillekeurige ereksie kry
- as u pupille verwyd is
- as u naar is of braak
- as u hardlywig is
- as u probleme het om te urineer.

As u enige newe-effekte opmerk wat nie in hierdie blad genoem word nie, moet u u dokter of apteker asseblief in kennis stel.

BEWARING EN WEGDOENING VAN PHOLTEX PLUS
Hou alle medisyne buite bereik van kinders.
Bewaar teen of benede 30 °C in 'n koel, droë plek. Hou dig geslote. Moenie in die yskas bêre nie. Skud bottel voor gebruik. Gee alle ongebruikte medisyne terug aan u apteker. Ongebruikte medisyne moet nie in dreinering- of rioolstelsels (bv. toilette) gegooi word nie.

AANBIEDING VAN PHOLTEX PLUS
PHOLTEX PLUS word verpak in bruin plastiekbottels van 100 ml of 200 ml met 'n plastiekprop, verpak in 'n gedrukte kartondoos.

AANBIEDING VAN PHOLTEX PLUS
PHOLTEX PLUS is 'n helder rooi, effens viskose vloeistof met die reuk van framboos en vla.

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