
1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

PHOLTEX JUNIOR, Pholcodine 5 mg/5 ml syrup.

Each 5 ml contains: Pholcodine 5 mg

Preservative: Sodium benzoate 0,2 % *m/v*

Contains sugar:

Sorbitol 1,750 g/ 5ml.

Contains sweetener:

Sodium saccharin 0,75 mg/5 ml

Read all of this leaflet carefully before you start taking Pholtex Junior

- Keep this leaflet. You may need to read it again.
- Do not share Pholtex Junior with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 5 days.

What is in this leaflet

1. What Pholtex Junior is and what it is used for
2. What you need to know before you take Pholtex Junior
3. How to take Pholtex Junior
4. Possible side effects
5. How to store Pholtex Junior
6. Contents of the pack and other information

1. What Pholtex Junior is and what it is used for



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Pholtex Junior is a medicine which helps relieve a dry non-productive cough.

2. What you need to know before give Pholtex Junior

Do not give Pholtex Junior:

- If your child is allergic to any of the ingredients in this medicine (see “What is in this medicine”)
- If your child has liver or kidney failure
- If your child has difficulty breathing
- If your child has long-term lung problems or an infection which produces lots of phlegm on the chest
- If you are giving your child monoamine oxidase inhibitors (for depression), or have given them in the last 14 days
- If you are giving your child any other cough and cold medicines
- If your child has an intolerance to some sugars (sorbitol), unless their doctor tells you to
- If your child has ever developed a severe skin rash or skin that peels, blisters and / or sores in the mouth after taking any pholcodine-containing products.
- if you are pregnant or breastfeeding.

Do not give Pholtex Junior to children under the age of 2 years old.

Take special care with Pholtex Junior and tell your doctor or pharmacist:

- If your child has a long-term cough or asthma (do not give this medicine to your child if they are wheezing or if they are having an asthma attack)
- If your child has a cough which produces lots of phlegm
- Before use if the person who will be taking this medicine has a history of drug abuse, Pholcodine is an opioid and addiction is observed with opioids as a class.
- If your child has other liver or kidney problems (see “Do not give”)


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Other important information

If your child develops a severe rash or any of the skin symptoms below, stop giving this medicine and contact or see a doctor immediately. Serious skin reactions, including acute generalized exanthematous pustulosis (AGEP), have been reported with the use of pholcodine. AGEP is a generalized, red, scaly rash with bumps under the skin and vesicles associated with fever. Most common location: mainly located on the folds of the skin, the trunk and the upper limbs. The highest risk of serious skin reactions occurrence is especially during the first week of treatment.

If your child goes into hospital for an operation, tell the doctor that you are giving this medicine.

Other medicines and Pholtex Junior

Always tell your health care provider if you are giving any other medicines. (This includes complementary or traditional medicines.)

Before you give this medicine, make sure that you tell your pharmacist about ANY other medicines you might be giving your child at the same time, particularly the following:

- Water tablets (diuretics) and medicines to treat high blood pressure. Also, blood pressure medicines antihypertensives), this may further decrease blood pressure;
- Medicines that may make your child sleepy or feel drowsy such as strong painkillers or medicines for epilepsy. Medicines for mood disorders, such as tricyclic antidepressants and phenothiazines, this may increase the sedative effect;
- central nervous system depressants for example sleeping tablets and tranquilizers, this may increase the sedative effect;
- Medicines for depression or other mental health conditions (anti-depressants known as monoamine-oxidase inhibitors (MAOI). Pholcodine should not be taken at the same time or within 14 days of stopping MAOI, this may increase your blood pressure severely)
- neuromuscular blocking medicines (anaesthetics used during surgery), this may cause a severe allergic reaction (anaphylaxis).


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If you are unsure about interactions with any other medicines, talk to your pharmacist. This includes medicines prescribed by your doctor and medicine you have bought for child, including herbal and homeopathic remedies.

Pholtex Junior with alcohol

Do not consume alcohol while taking this medicine as this might increase drowsiness.

Pregnancy, breastfeeding and fertility

The use of Pholtex Junior has not been tested during pregnancy, breastfeeding and fertility.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

Pholtex Junior may cause drowsiness and dizziness. Do not drive or operate machinery until you know how the medicine will affect you.

It is not always possible to predict to what extent Pholtex Junior may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which Pholtex Junior affects them.

Pholtex Junior contains sorbitol

Sorbitol may have a laxative effect, and may affect blood sugar control in patients with diabetes mellitus. Patients with the rare hereditary condition of sorbitol intolerance should not take Pholtex Junior.

3. HOW TO TAKE PHOLTEX JUNIOR

Do not share medicines prescribed for you with any other person.

Always take Pholtex Junior exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is as follows:

Children 5 – 12 years:

2,5 to 5 ml (Half to one medicine measure) three to four times a day.


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Children 2 – 5 years:

2,5 ml (half a medicine measure) three times a day.

Pholtex Junior should not be given to children under 2 years of age.

If you have the impression that the effect of Pholtex Junior is too strong or too weak, talk to your doctor or pharmacist.

If you take more Pholtex Junior than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre. The following symptoms may be experienced in case of overdosage:

- drowsiness
- restlessness
- excitement
- impaired balance or coordination (ataxia)
- difficulty breathing.

If you forget to take Pholtex Junior:

Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

Pholtex Junior can have side effects. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking Pholtex Junior and tell your doctor immediately or go to the casualty department at your nearest hospital:


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- severe skin rash/ pustules
- swollen face, lips, tongue
- difficulty breathing.

These are all very serious side effects. If you have them, you may have had a serious reaction to Pholtex Junior. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- nausea, vomiting, constipation
- drowsiness, dizziness
- difficulty coughing up mucous or saliva
- excitation, confusion.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**” found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of Pholtex Junior.

Alternately you can contact iNova Pharmaceuticals (Pty) Ltd at +27 11 087 0000.

www.inovapharma.co.za

5. How to store Pholtex Junior

Keep all medicines out of the reach and sight of children.

Store at or below 30 °C.

Do not use after the expiry date stated on the carton or label.

Return all unused medicine to your pharmacist.


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Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Pholtex Junior contains

- The active substance is pholcodine.
- The other ingredients are citric acid, disodium edetate, hydroxyethyl cellulose, purified water, sodium citrate dehydrate, sodium saccharin, sorbitol and Tutti Frutti flavour.
- Preservative: sodium benzoate 0,2 % *m/v*.

What Pholtex Junior looks like and contents of the pack

Pholtex Junior is a colourless, slightly viscous syrup with a fruity flavour. It is packed in 100 ml and 200 ml amber plastic or glass bottles with a plastic screw on cap.

Holder of the Certificate of Registration

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