

Proposed patient information leaflet for BENYLIN FOUR FLU TABLETS

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

BENYLIN FOUR FLU TABLETS

Diphenhydramine hydrochloride / pseudoephedrine hydrochloride / paracetamol

Sugar free.

Read all of this leaflet carefully because it contains important information for you.

- BENYLIN FOUR FLU TABLETS is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to give BENYLIN FOUR FLU TABLETS carefully to get the best results from it.

- Do not share BENYLIN FOUR FLU TABLETS with any other person.
- Keep this leaflet. You may need to read it again.
- 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.

What is in this leaflet

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

1. What BENYLIN FOUR FLU TABLETS is and what it is used for

BENYLIN FOUR FLU TABLETS contains an analgesic (paracetamol), an antihistamine (diphenhydramine) and a decongestant (pseudoephedrine). It belongs to a class of medicines which is used to relieve the symptoms of colds and flu. BENYLIN FOUR FLU TABLETS is used to help relieve cough, congestion, fever and body pains. Paracetamol is an analgesic and an antipyretic which acts to relieve pain and fever (high temperature). Diphenhydramine is an antihistamine which helps to relieve coughing. Pseudoephedrine is a decongestant which helps unblock stuffy noses.

2. What you need to know before you take BENYLIN FOUR FLU TABLETS

Do not take BENYLIN FOUR FLU TABLETS if you or your child:

- Are hypersensitive (allergic) to diphenhydramine, pseudoephedrine hydrochloride, paracetamol or any of the other ingredients of BENYLIN FOUR FLU TABLETS (listed in section 6).
- Suffer from high blood pressure, heart disease or an over-active thyroid.
- Have phaeochromocytoma (rare tumour which affects your heart rate and blood pressure).
- Suffer from closed angle glaucoma (pressure in the eye).
- Suffer from severe liver problems.
- Are going to have surgery and cyclopropane, halothane, or other halogenated anaesthetic medicines are going to be used.
- Are taking medicines known as monoamine oxidase inhibitors (MAOIs).

Warnings and precautions

Take special care with BENYLIN FOUR FLU TABLETS:

- If you or your child suffer from any respiratory diseases such as emphysema (lungs are enlarged and damaged), persistent inflammation of the bronchi (chronic bronchitis) or acute or persistent bronchial asthma.
- If you have prostate disease or you or your child have difficulty urinating or emptying your bladder (urinary retention).
- If you are regularly consuming a large amount of alcohol (chronic alcoholism).
- If you or your child take medicines which make you drowsy or give you a dry mouth (sometimes called anti-cholinergics) while you are taking BENYLIN FOUR FLU TABLETS the chances of these side-effects are increased (see **Other medicines and BENYLIN FOUR FLU TABLETS**).
- If you or your child suffer from fits (seizures).
- If you are elderly.
- If you or your child suffer from liver or kidney disease.
- If you or your child are diabetic.
- If you suffer from a persistent cough such as occurs with asthma or produce a lot of mucus (phlegm).

BENYLIN FOUR FLU TABLETS can make some people feel drowsy or cause difficulty in concentration. Make sure that you or your child are not affected if you are going to do anything where you need to be alert. Be especially careful if you are taking another medicine which may also cause drowsiness.

If symptoms persist or get worse, or if new symptoms occur, you should stop using BENYLIN FOUOR FLU TABLETS and consult a doctor.

Stop taking BENYLIN FOUR FLU TABLETS if the following happens to you or your child:

- You suddenly develop a skin rash, or small pustules, with or without fever, after starting treatment with BENYLIN FOUR FLU TABLETS.
- You suddenly develop symptoms such as pain in your stomach area, blood in your stool, nausea (feeling sick) or vomiting (being sick) (signs of ischaemic colitis).

Other medicines and BENYLIN FOUR FLU TABLETS

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

Talk to your doctor or pharmacist before taking or giving BENYLIN FOUR FLU TABLETS to your child if you or your child are taking:

- monoamine oxidase inhibitors (MAOIs) (used to treat depression), or antidepressants (medicines used to treat mood disorders) (see **Do not take BENYLIN FOUR FLU TABLETS**);
- decongestants, appetite suppressants or stimulants;
- medicines for high blood pressure;
- medicines which make you drowsy or give you a dry mouth (sometimes called anti-cholinergic medicines);
- warfarin (used to thin your blood and prevent blood clots from forming);
- tranquillisers or sedatives (medicine used to relax muscles or decrease anxiety);
- quinidine (used to treat heart rhythm disorders);
- antidepressants (used to treat depression).

Do not take BENYLIN FOUR FLU TABLETS with other medicines containing paracetamol, diphenhydramine or pseudoephedrine.

BENYLIN FOUR FLU TABLETS with food, drink and alcohol

Do not take alcohol-containing products while taking BENYLIN FOUR FLU TABLETS.

Pregnancy, breastfeeding and fertility

Safety and efficacy of BENYLIN FOUR FLU TABLETS during pregnancy and lactation have not been established.

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 BENYLIN FOUR FLU TABLETS.

BENYLIN FOUR FLU TABLETS should not be used during pregnancy or lactation unless the potential benefit of treatment to the mother outweighs the possible risks to the developing fetus or breastfeeding infant. *Ask a healthcare professional before use if you are pregnant or breastfeeding.*

Driving and using machines

BENYLIN FOUR FLU TABLETS can cause side effects, such as sedation, drowsiness, dizziness or blurred vision.

Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how BENYLIN FOUR FLU TABLETS affect you.

3. How to take BENYLIN FOUR FLU TABLETS

Do not share medicines with any other person.

For adults, the elderly and children 12 years and older:

The usual dose is two tablets 4 times a day. Do not exceed 8 tablets in 24 hours.

For children aged 6 to less than 12 years:

The usual dose is one tablet 4 times a day. Do not exceed 4 tablets in 24 hours.

Children under 6 years

Not recommended.

For oral use only.

BENYLIN FOUR FLU TABLETS can be taken with or without food.

Always take BENYLIN FOUR FLU TABLETS 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.

If you have the impression that the effect of BENYLIN FOUR FLU TABLETS is too strong or too weak, tell your doctor or pharmacist.

If you take more BENYLIN FOUR FLU TABLETS than you should

In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take along any medicine that are left and the carton so that the hospital can easily tell what medicine you have taken.

Immediate medical advice should be sought in the event of an overdose even if you feel well because of the risk of delayed serious liver damage.

If you forget to take BENYLIN FOUR FLU TABLETS

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose.

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

4. Possible side effects

BENYLIN FOUR FLU TABLETS can have side effects.

Not all side effects reported for BENYLIN FOUR FLU TABLETS are included in this leaflet.

Should your or your child's general health worsen or if you experience any untoward effects while taking BENYLIN FOUR FLU TABLETS, please consult your health care provider for advice.

If any of the following happens, stop taking or giving BENYLIN FOUR FLU TABLETS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash, hives or itching;
- fainting.

These are all very serious side effects. If you or your child have them, you may have had a serious allergic reaction to BENYLIN FOUR FLU TABLETS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- bleeding or bruising more easily than normal;
- frequent infections such as fever, severe chills, sore throat or mouth ulcers;
- fits (seizures);
- stroke (sudden numbness or weakness in the face, arm or leg, especially on one side of your body);
- changes in the way your heart beats (beating faster, slower or irregular);
- chest pain;
- heart failure (shortness of breath, fatigue and weakness, swelling of the legs, ankles and feet, rapid or irregular heartbeat, persistent cough with white or pink phlegm);
- heart attack (pain in your chest, back, jaw and other areas of your upper body that lasts more than a few minutes or that goes away and comes back, shortness of breath);

- difficulty breathing;
- water in your lungs (trouble breathing or feeling like you are suffocating, a bubbly, wheezing or gasping sound when you breathe);
- sudden skin eruptions (pustules) arising within large areas of red swollen skin;
- difficulty urinating, pain when urinating, inability to empty your bladder completely;
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Side effect occurring frequently:

- sedation (depressed consciousness);
- difficulty falling or staying asleep (insomnia);
- nervousness;
- headache or dizziness;
- sleepiness (varying from drowsiness to deep sleep), lack of energy, lack of coordination;
- feeling abnormally excited;
- slowing down of physical and emotional reactions, including speech and affect;
- blurred vision;
- upset stomach, nausea (feeling sick), dry mouth;
- thickened mucus;
- abnormal physical weakness or lack of energy.

Side effects occurring less frequently:

- anaemia (fatigue, loss of energy, pale skin, cramps in your legs, difficulty with concentration);

- pain in the upper, middle region of your stomach;
- nausea (feeling sick);
- redness of your skin;
- lack/loss of appetite (anorexia), increased appetite, altered metabolism including changes in your blood sugar levels;
- unrealistic feeling of well-being;
- feeling anxious, confused, irritable, agitated, depressed, restless;
- psychosis (a mental disturbance in which you cannot distinguish between reality and imagination);
- seeing or hearing things that do not exist;
- tremors (involuntary trembling or shaking of your hands and feet);
- extrapyramidal symptoms (characterised by continuous spasms and muscle contractions);
- abnormal coordination;
- tingling or numbness of your hands and feet (pins and needles);
- ringing in your ears;
- low blood pressure or high blood pressure;
- chest discomfort, chest discomfort, dry throat, nasal dryness;
- vomiting (being sick), diarrhoea, constipation, increased saliva, pain in your stomach, indigestion;
- sweating;
- feeling weak, including muscle weakness;
- increased liver enzymes (transaminase) when blood tests are done.

Side effects occurring with unknown frequency:

- too low levels of potassium when blood tests are done (weakness and fatigue, muscle cramps and pain).

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 Reactions Reporting Form**”, found online under SAHPRA’s publications: <http://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of BENYLIN FOUR FLU TABLETS.

For further information, please contact the Johnson & Johnson call centre on 0860 410032 (landline).

5. How to store BENYLIN FOUR FLU TABLETS

- Keep in the original container until required for use.
- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in a dry place, protected from light.
- Do not use after the expiry date stated on the label / carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BENYLIN FOUR FLU TABLETS contains

Each film-coated tablet contains the active ingredients: 12, 5 mg Diphenhydramine hydrochloride, 22,5 mg Pseudoephedrine hydrochloride and 500,0 mg Paracetamol.

The other ingredients are croscarmellose sodium, crospovidone (E1202), magnesium stearate (E572), microcrystalline cellulose (E460(i)), Opadry Yellow (colourant, containing hypromellose (E464), macrogol 6000 (E1521), Sunset Yellow FCF (E110), talc (E553b), titanium dioxide (E171) and quinoline yellow aluminium lake), povidone (E1201), pregelatinised maize starch, stearic acid (E570).

What BENYLIN FOUR FLU TABLETS looks like and contents of the pack

Orange, oval, film coated tablets.

Opaque white PVC blister packs containing 24 tablets packed into a carton.

Holder of certificate of registration

Johnson & Johnson (Pty) Ltd.

241 Main Road

Retreat

7945

South Africa

This leaflet was last revised in

1 March 2022.

Registration number

33/5.8/0509