
BENYLIN® FOUR FLU LIQUID
PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

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BENYLIN® FOUR FLU LIQUID

Diphenhydramine hydrochloride / pseudoephedrine hydrochloride / paracetamol.

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

BENYLIN® FOUR FLU LIQUID is available without a doctor's prescription, for you or your child to treat a mild illness.

Nevertheless, you still need to use or give BENYLIN® FOUR FLU LIQUID carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BENYLIN® FOUR FLU LIQUID with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see your doctor if your or your child's symptoms worsen or do not improve after 10 days.

What is in this leaflet

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

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

BENYLIN® FOUR FLU LIQUID 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 LIQUID is used to help relieve cough congestion, fever and body pains.

Paracetamol is an analgesic and an antipyretic which means that it helps 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 use BENYLIN® FOUR FLU LIQUID

Do not use or give BENYLIN® FOUR FLU LIQUID

- If you or your child are hypersensitive (allergic) to diphenhydramine hydrochloride, paracetamol, pseudoephedrine hydrochloride or any of the other ingredients in BENYLIN® FOUR FLU LIQUID (see What BENYLIN® FOUR FLU LIQUID contains).
- If you or your child suffer from high blood pressure, heart disease, angina (chest pain), hyperexcitability or an over-active thyroid.
- If you or your child have phaeochromocytoma (rare tumour which affects your heart rate and blood pressure).
- If you or your child suffer from glaucoma (pressure in the eye).
- If you or your child suffer from severe liver disease.
- If you or your child are taking medicines known as monoamine oxidase inhibitors (MAOIs) (including linezolid) or if you have stopped treatment with such medicines within the last 14 days.
- If you or your child are going to have surgery and cyclopropane, halothane, or other halogenated anaesthetic medicines are going to be used.

BENYLIN® FOUR FLU LIQUID should not be used in children under 12 years of age.

Warnings and precautions

Take special care with BENYLIN® FOUR FLU LIQUID

- If you or your child have any heart, kidney or liver problems (including alcoholic liver disease) contact your doctor before using BENYLIN® FOUR FLU LIQUID.
- If you or your child have thyroid problems or diabetes mellitus (high blood sugar).
- If you or your child have difficulty passing water (urinary retention) or you have prostate disease.
- Do not take dosages in excess of those recommended. BENYLIN® FOUR FLU LIQUID may cause severe damage to your liver or kidneys.
- Do not use continuously for more than 10 days without consulting a doctor.
- BENYLIN® FOUR FLU LIQUID 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 medicine which may also cause drowsiness, including alcohol, sedatives, tranquilisers or other central nervous system depressants.
- If you or your child are taking medicines which make you drowsy or give you a dry mouth (sometimes called anti-cholinergics) while you or your child are taking BENYLIN® FOUR FLU LIQUID, the chances of these side effects are increased.
- If you are regularly consuming a large amount of alcohol (chronic alcoholism). Do not use alcohol while taking BENYLIN® FOUR FLU LIQUID.
- If you or your child suffer from a persistent cough such as occurs with asthma or produce a lot of mucus (phlegm).
- If you or your child have any of the following respiratory conditions: emphysema, asthma or bronchitis contact your doctor before using BENYLIN® FOUR FLU LIQUID.

- If you or your child are taking any medicines containing paracetamol, pseudoephedrine or diphenhydramine, even ones used on your skin.
- If you or your child are taking medicines prescribed by your doctor, particularly anti-depressants or atropine.

Stop using BENYLIN® FOUR FLU LIQUID if the following happens to you:

- If you or your child experience restlessness, hallucinations or sleep disturbances.
- If you or your child suddenly develop a skin rash, or small pustules, with or without fever, after starting treatment with BENYLIN® FOUR FLU LIQUID. Serious skin reactions occur very rarely.
- If you or your child 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).

If symptoms persists or gets worse, or if new symptoms occur, speak to your doctor.

Children and adolescents

Do not use BENYLIN® FOUR FLU LIQUID in children under 12 years of age.

Other medicines and BENYLIN® FOUR FLU LIQUID

Always tell your health care professional if you are taking or giving your child any other medicines. This includes complementary or traditional medicines. If you are not sure about any of the medicines you or your child are using or taking, show the bottle or pack to your pharmacist or health care professional for advice.

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

- monoamine oxidase inhibitors, or antidepressants (to treat mood disorders)

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- hypnotics (sleeping tablets including barbiturates).
 - sedatives, barbiturates, neuroleptic medicines or tranquillisers (medicines used to relax muscles or decrease anxiety).
 - antipsychotics (medicines used to treat mood disorders).
 - decongestants, appetite suppressants or stimulants (or sympathomimetic medicines).
 - medicines used to treat high blood pressure.
 - medicines used to treat eye conditions or occasionally bowel disorders (atropine)
 - *metoclopramide* or *domperidone* (used to treat nausea and vomiting).
 - *cholestyramine* (used to treat high cholesterol).
 - *anticoagulants* (medicines that thin the blood, such as warfarin).
 - antibacterial medicines, including linezolid (used to treat bacterial infections).
 - cardiac glycosides or quinidine (used to treat heart rhythm disorders).
 - probenecid (used to treat gout).

Do not take BENYLIN® FOUR FLU LIQUID with other medicines containing paracetamol, diphenhydramine, pseudoephedrine or medicines that have similar acting components.

BENYLIN® FOUR FLU LIQUID should not be taken with alcohol.

BENYLIN® FOUR FLU LIQUID with food, drink and alcohol

Do not take BENYLIN® FOUR FLU LIQUID with alcohol.

Pregnancy, breastfeeding and fertility

Safety in pregnancy and during breastfeeding has not been established.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care professional for advice before taking BENYLIN® FOUR FLU LIQUID.

Driving and using machines

BENYLIN® FOUR FLU LIQUID can make some people feel drowsy, dizzy or have blurred vision.

Make sure that you or your child are not affected when you or your child need to be alert.

Do not drive a motor car, operate machinery or climb dangerous heights if you are affected, as weakened decision-making could lead to accidents.

BENYLIN® FOUR FLU LIQUID contains sodium benzoate

Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to use BENYLIN® FOUR FLU LIQUID

DO NOT TAKE MORE THAN THE RECOMMENDED DOSE.

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

- For oral use only.
- Shake the bottle before use.

The usual dose is:

Adults, the elderly and children over 12 years:

20 mL (four 5 mL medicine measurements) four times daily as required.

Timing between doses should not be less than 4 hours.

Food does not affect the amount of paracetamol that is absorbed into the body. High fat meals will delay the absorption of pseudoephedrine.

Maximum daily dose: Do not exceed four doses in 24 hours.

Children under 12 years of age: Not recommended.

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

If you take more BENYLIN® FOUR FLU LIQUID than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take along any medicines that is left and the carton so that the hospital can easily tell what medicine you have taken or given your child.

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

If you forget to use BENYLIN® FOUR FLU LIQUID

You should only use or give BENYLIN® FOUR FLU LIQUID as required following the recommended dose.

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

Do not take or give two doses at the same time.

4. Possible side effects

BENYLIN® FOUR FLU LIQUID can have side-effects.

Not all side effects reported for BENYLIN® FOUR FLU LIQUID are included in this leaflet. Should yours or your child's general health worsen or if you or your child experience any untoward effects while using BENYLIN® FOUR FLU LIQUID, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using/giving BENYLIN® FOUR FLU LIQUID 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 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 LIQUID. 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:

Less frequent:

- blood disorders, including symptoms such as becoming unusually tired, unexpected bruising or bleeding and getting more infections (such as colds) than usual,
- increased heartbeat (palpitations) and irregular, fast or slow heart rate,
- kidney problems, leading to less urine than is normal for you, difficulty in passing urine, painful urination (especially in patients with an enlarged prostate),
- shortness of breath.

Frequency not known:

- heart attack (chest pain or tightness in your chest, pain radiating into your arms or back, shortness of breath, tiredness, light-headedness or dizziness),
- very serious skin disorders, such as acute generalised exanthematous pustulosis (which include a painful red or purplish rash with fluid filled blisters),
- allergic reactions to other medicines containing sympathomimetic medicines (stimulants or appetite suppressants and medicines used to treat congestion and asthma),
- convulsions (which may precipitate fits if you or your child is epileptic),
- tightness of the chest,
- stroke (characterised by sudden numbness or weakness of the face, arm or leg (especially on one side of the body), slurred speech,

- abnormal blood test results for liver function tests, yellowing of the skin and eyes, dark urine, and tiredness may be symptoms of liver problems,
- ischaemic colitis (pain in your stomach area, blood in your stool, nausea or vomiting).

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

Tell your doctor if you notice any of the following:

Frequent:

- drowsiness to deep sleep, including some difficulty performing tasks that require attention and concentration,
- loss of energy, dizziness or lack of coordination.

Less frequent:

- high blood pressure,
- restlessness, sleep disturbances (lack of sleep), irritability, anxiety, tremor (shakiness), confusion, mood changes,
- extrapyramidal symptoms (characterised by continuous spasms and muscle contractions),
- low blood pressure (especially in elderly patients), including dizziness,

- nausea and sickness, vomiting, diarrhoea (upset stomach), constipation, anorexia (reduced appetite), increased appetite, pain in your upper stomach area, increased saliva,
- photosensitivity of your skin, changes in results when skin tests are done, increased sweating
- pancreatitis (pain in your stomach are, radiating to your back, fever, nausea, vomiting),
- low levels of potassium in your body (muscle cramps, changes in the way your heart beats),
- headache,
- flushing, weakness

Frequency not known:

- hallucinations, excitability, and psychosis (a mental disturbance in which you cannot distinguish between reality and imagination),
- euphoria, stimulation, depression,
- paraesthesia (tingling or numbness of your hands and feet (pins and needles)), agitation, inability to sit still,
- blurred vision, tinnitus (ringing in your ears),
- dry mouth, thickened mucus,
- pain in your stomach area, indigestion,
- muscle weakness,
- changes in your metabolism, including blood sugar levels,
- jittery feeling.

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 LIQUID.

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

5. How to store BENYLIN® FOUR FLU LIQUID

- Store at or below 25 °C.
- Keep the medicine in the original container.
- Protect from light.
- Store all medicines out of reach of children.
- Keep the bottle tightly closed.
- Do not use your medicine after the expiry date stated on the labelling.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BENYLIN® FOUR FLU LIQUID contains

The active substances are diphenhydramine hydrochloride 25,0 mg, paracetamol 1 000,0 mg and pseudoephedrine hydrochloride 45,0 mg per 20 mL of liquid.

The liquid contains sodium benzoate 0,2 % *m/v* as preservative and alcohol 9,9 % *v/v*.

The other ingredients are citric acid (E331), colourants (D & C Yellow No. 10, patent blue V and Ponceau 4R), denatured alcohol menthol, flavourants (milk cream, eucalyptol, honey, lemon, and menthol), glycerol (E422), polyethylene glycol (E1521), propylene glycol (E1520), purified water, sodium benzoate (E211), sodium carboxymethylcellulose (E466), sodium citrate (E331), and sodium saccharin (E954).

What BENYLIN® FOUR FLU LIQUID looks like and contents of the pack

BENYLIN® FOUR FLU LIQUID is a clear, orange liquid with a characteristic honey and lemon odour and taste.

Round, amber glass bottle of 100 and 200 mL, with a plastic measuring cup.

Holder of certificate of registration

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