

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. Keep this leaflet. You may need to read it again. If you have more questions, ask your doctor or pharmacist. This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

WHAT IN THIS LEAFLET:

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2. Before you take your medicine
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1. What your medicine is and what it is used for

Paracetamol works by relieving pain and reducing high temperature and fever. Your medicine is for effective relief from: mild to moderate pain including headache, migraine, sharp nerve pain (neuralgia), toothache, sore throat, period pains, aches and pain, symptomatic relief of rheumatic aches and pains, influenza symptoms, feverishness and feverish colds.

2. Before you take your medicine

Please read the following information. Do not give to children under 6 years.

Do not take if you:

are taking any other products that contain paracetamol are allergic to paracetamol or any of the other ingredients.

Take special care and talk to a pharmacist or your doctor before taking this medicine if you are:

suffering from liver or kidney disease (including alcoholic liver disease) or G-6-PD deficiency (an hereditary condition leading to low red blood cell counts).

Taking other medicines

Do not use this medicine if you are taking medicines that reduce the clotting of the blood (e.g. warfarin). Talk to your doctor or a pharmacist if you are taking some antibiotics (chloramphenicol), anti-sickness treatments (metoclopramide, domperidone), some treatments for diarrhea caused by gall bladder disease, or lipid lowering drugs (cholestyramine).

3. How to take your medicine

For oral administration and short term use only

Dosage:

Adults, the elderly and young persons aged 16 or over:

The minimum effective dose should be used for the shortest time necessary to relieve symptoms. Take 2 tablets up to 4 times a day, as required. The tablets should be taken with water. Take only as much as you need to relieve your symptoms and leave at least 4 hours between each dose. Do not take more than 8 tablets in 24 hours.

For children 6 to 9 years of age:

Give ½ a tablet with a drink of water, every 4 hours

as required.

For children 10 to 11 years of age:

Give 1 tablet with a drink of water, every 4 hours as required.

For adolescents 12 to 15 years of age:

Give 1 to 1 ½ a tablet with a drink of water, every 4 hours as required.

For all children's dosing, give only as much as you need to relieve symptoms and leave at least 4 hours between each dose.

Do not give more than 4 doses in 24 hours

3. How to take your medicine

Do not take with any other paracetamol-containing products.

Do not give to children under 6 years of age.

Do not exceed the stated dose.

If you take more tablets than you should:

Talk to a doctor at once if you take too much of this medicine, even if you feel well.

This is because too much paracetamol can cause delayed, serious liver damage.

Bring any remaining medicine with you to show the doctor.

4. Possible Side Effects:

Like all medicines, your medicine can cause side effects, although not everybody gets them.

You can reduce the chances of experiencing side effects by using the minimum dose required. Side effects may be more serious in elderly patients.

If you experience any of the following serious effects STOP taking this medicine

immediately and contact your doctor or pharmacist:

Severe allergic reactions: difficulty breathing, skin rash, swollen facial features or a runny nose.

Very rare cases of serious skin reactions have been reported. Symptoms could include skin reddening, blisters or rash.

Other possible side effects

If any of the following side effects get serious, or if you notice any side effect not listed in

this leaflet, please tell your doctor or pharmacist:

Occasionally the blood does not clot well, which may result in easy bruising or bleeding.

Rarely, a severe reduction in the number of white blood cells, which makes infections more likely.

Other rare side effects like shortness of breath.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By

reporting side effects you can help provide more information on the safety of this medicine.

5. How to store your medicine

Do not use this medicine after the expiry date shown on the end of the carton.

Do not store above 25°C.

Keep out of sight and reach of children

6. Further Information

What does this medicine contain?

The active substance is Paracetamol. Your medicine contains 500 mg of Paracetamol.

Each tablet also contains:

- microcrystalline cellulose,
- colloidal silica,
- povidone,
- croscarmellose sodium,
- magnesium stearate.

The Marketing Authorisation Holder:

ZADA Pharmaceuticals Ltd.

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75 300 Lukavac

Bosnia and Herzegovina

Data and number of first authorisation / renewal of the authorisation in BIH :

Paracetamol ZADA 20x500 mg tablets:

04-07.3-1-4906/16 from 14.06.2017.

Paracetamol ZADA 500x500 mg tablets:

04-07.3-2-6612/16 from 16.12.2016.