PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0 Pack sizes smaller than 25 tablets

ZYPOL 500 mg tablets

Paracetamol

Contains sugar: Each tablet contains 20 mg sucrose per tablet.

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

- ZYPOL are available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ZYPOL carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share ZYPOL 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 after a few days.

What is in this leaflet

1. What ZYPOL is and what it is used for

ZYPOL contain paracetamol, a medicine which has analgesic (pain reliever) and antipyretic (reduces fever) activity. ZYPOL are therefore used in the relief of mild to moderate pain and fever such as headaches, toothache and pain associated with colds and flu.

2. What you need to know before you take ZYPOL

Do not take ZYPOL if:

- you are hypersensitive (allergic) to paracetamol or any of the other ingredients of ZYPOL.
- you suffer from severe liver function impairment.

Warnings and precautions

Special care should be taken with ZYPOL:

ZYPOL contain paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor hospital or Poison Centre must be contacted immediately.

- if you take more ZYPOL than you should as it can cause damage to your liver.
- if pain or fever persists or gets worse at the recommended dosage, or if new symptoms occur.
- do not take ZYPOL continuously for pain for more than 7 days in adults (5 days for children); and for fever for more than 3 days. Consult your doctor if your symptoms worsen or do not improve after these periods.
- when suffering from hepatitis or alcoholism, or recovering from any form of liver disease.
- if you are suffering from moderate renal failure or are on dialysis as this may increase the concentration of ZYPOL in the blood.
- if you are diagnosed with renal impairment, chronic malnutrition or dehydration.
- if you experience any serious skin reactions, often together with flu-like symptoms after you start taking ZYPOL. Stop taking ZYPOL and seek urgent advice from your doctor. The skin reactions such as swelling, itching, red severe rash especially those covering the whole body (appearing as allergic wheals) may progress to widespread blistering or peeling of the skin and can be a serious reaction to ZYPOL, called severe cutaneous adverse reactions (SCARs) (see section 4, Possible side effects).
- Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Children

Do not give ZYPOL to children between the ages of 0 and 6 years because it is unlikely to be safe.

Other medicines and ZYPOL

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- medicines that may be damaging or destructive to liver cells.
- medicines that increase liver enzymes and may therefore result in a further risk for liver damage and a possible decrease in therapeutic effect of ZYPOL.
- certain medicines for nausea and vomiting like metoclopramide and domperidone which may accelerate the absorption of ZYPOL.
- medicines used to treat gout and high blood levels of uric acid, such as probenecid, can decrease the elimination of ZYPOL from the body.
- certain medicines, such as cholestyramine, that are used to lower high cholesterol levels, may reduce the absorption of ZYPOL if given within one hour after taking ZYPOL.
- prolonged concurrent use of ZYPOL with salicylates, such as aspirin, increases the risk of adverse kidney effects.
- chronic use of isoniazid and/or rifampicin, antibiotic medicines often prescribed for tuberculosis. It may increase the risk of liver damage when combined with ZYPOL, even at recommended doses.
- warfarin or other blood thinning medicines (anticoagulants) together with ZYPOL may increase the risk of bleeding. Your doctor might monitor your blood clotting factors more regularly.
- medicines used for epilepsy, such as carbamazepine, phenobarbital, phenytoin, or primidone. Your doctor might lower the dosage of ZYPOL.
- zidovudine used to treat viral infections and co-trimoxazole used to treat bacterial infections. These medicines together with ZYPOL can cause damage to the liver.
- the effect of Interferon alfa used to treat cancers and viral infections, can be increased when used together with ZYPOL and your doctor might change the dose.

Pregnancy, breastfeeding and fertility

ZYPOL are generally considered safe for use during pregnancy, if used infrequently (not daily / not on most days).

ZYPOL are distributed into breastmilk, in amounts too small to be considered harmful to a breastfed infant. No significant adverse effects have been seen in breastfed infants whose mothers received paracetamol as contained in ZYPOL.

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 healthcare professional for advice before taking ZYPOL.

Driving and using machinery

It is not always possible to predict to what extent ZYPOL 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 ZYPOL affects them.

3. How to take ZYPOL

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

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

Children under 6 years: Not recommended.

Children 6 – 12 years: Take ½ - 1 tablet every 6 hours orally. Not more than 4 doses to be taken in any 24-hour period for not longer than 5 days.

Children over 12 years: Take 1 tablet every 4 – 6 hours orally. Not more than 8 tablets to be taken in any 24-hour period.

Adults: Take 1 – 2 tablets every 4 – 6 hours orally. Not more than 8 tablets to be taken in any 24-hour period.

DO NOT EXCEED THE RECOMMENDED DOSE.

If you take more ZYPOL than you should

ZYPOL contain paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.

Paracetamol toxicity is increased in patients who have taken repeated high doses (greater than 5 - 10 g/day) of paracetamol for several days, in chronic alcoholism, chronic liver disease, AIDS, malnutrition, and with the use of medicines that induce liver microsomal oxidation such as barbiturates (medicine to treat anxiety), isoniazid (antibiotic to treat tuberculosis), rifampicin (medicine to treat tuberculosis), phenytoin (medicine to treat epilepsy) and carbamazepine (medicine to treat epilepsy).

Symptoms in the first 24 hours of paracetamol overdosage include pale skin, nausea, vomiting, anorexia and possibly abdominal pain. Mild symptoms during the first two days of acute poisoning, do not reflect the potential seriousness of the overdosage. Liver damage may become apparent 12 to 48 hours, or later after ingestion, initially by evaluation of the serum blood levels by your doctor. Liver damage may lead to a decrease in brain function (encephalopathy), coma and death. Acute kidney failure may develop even in the absence of severe liver damage. Abnormalities of glucose metabolism and metabolic acidosis (when too much acid accumulates in the body) may occur. Cardiac arrhythmias (irregular heartbeats) have also been reported. Overdose during pregnancy when metabolites of paracetamol crosses the placenta and which may result in toxic liver metabolites and cause liver toxicity in the foetus.

If you forget to take a dose of ZYPOL

Do not take a double dose to make up for forgotten individual doses. Take the dose as soon as you remember, but do not exceed the recommended daily dose.

4. Possible side effects

ZYPOL can have side effects.

Not all side effects reported for ZYPOL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ZYPOL, please consult your healthcare professional for advice.

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

- allergic reaction, e.g. swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing; rash or itching; fainting; low blood pressure (hypotension),
- serious skin reactions called severe cutaneous adverse reactions (SCARS). SCARS are a group of potentially very serious adverse drug reactions that can be fatal and involve the skin and mucous membranes (the moist, inner lining of some organs and body openings, such as the nose, mouth, lungs, and stomach). Examples of SCARs includes toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalized exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS)/ drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruption (FDE) (see also section 2, Warnings and precautions).

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

Tell your doctor if you notice any of the following:

The following side effects have been reported less frequently:

- feeling tired, pale skin, shortness of breath, light-headedness, dizziness or a fast heartbeat, increase in nose bleeds or unusual bleeding (blood test shows changes in the blood cell counts),
- loss of hearing,
- high blood pressure,

- inflammation of the pancreas (you may have pain in the upper part of your belly, nausea and vomiting),
- inflammation of the liver (you may feel nauseas, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine),
- pain caused by kidney stones,
- kidney problems (you may have blood in your urine, cloudy urine, change in how frequent you want to urinate),
- itching, red and inflamed skin.

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 or nurse. This includes any possible side effects not listed in this leaflet. 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 ZYPOL.

5. How to store ZYPOL

Store all medicines out of reach of children.

Store in a cool dry place, in well-closed containers, at or below 25 °C.

Protect from light.

Keep the blisters in the carton until required for use.

Do not use after the expiry date stated on the label / carton / bottle

Return all unused medicine to your pharmacist.

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

ZYPOL has a shelf life of 36 months if packed in securitainers.

ZYPOL has a shelf life of 24 months if packed in blisters.

ZYPOL has a shelf life of 15 months if packed in patient ready packs.

6. Contents of the pack and other information

What ZYPOL contain:

The active substance is paracetamol

Each ZYPOL Tablet contains 500 mg paracetamol.

The other ingredients are Starch Maize, Powdered Sucrose, Nipastat, Benzoic Acid, Gelatin, Green Apple Colour, Magnesium Stearate and Modified Starch.

What ZYPOL look like and contents of the pack

A flat, round, green tablet with a break line on one side.

The break line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Securitainers of 24 tablets.

PVC/Aluminium foil blister packs of 20 and 24 tablets.

White LDPE patient ready packs containing 20 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration and Manufacturer

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