Patient Information Leaflet

MINAFEN Syrup 120 mg / 5 ml

"For babies and children "

It is taken orally.

Active Ingredient: One scale (5 ml) contains 120 mg of paracetamol.

Excipients: Sorbitol (70%), glycerin 99.5%, polyethylene glycol 400, strawberry flavor, tutti frutti flavor, carboxymethylcellulose sodium, sucralose, sodium benzoate, sodium citrate dihydrate, carmoicin, citric acid monohydrate, purified water.

Please read this leaflet carefully before you start taking/using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others.
- When using this medicine, tell your doctor or doctor when you go to the hospital that you are taking it.
- Follow the instructions in these instructions. Do not use high or low doses other than the recommended dose.

In this leaflet:

Headlines are included.

1. WHAT IS MINAFEN AND WHAT IS IT USED FOR?

MINAFEN is a clear, pink-red (solution) syrup, containing 120 mg paracetamol in each scale (5 ml), and acts as a painkiller and antipyretic.

MINAFEN is supplied in a 100 ml and 150 ml bottle.

MINAFEN is used in the symptomatic treatment of mild and moderate pain and fever in children, not relieving symptoms.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MINAFEN

Do not take MINAFEN:
If;

- Hypersensitivity to paracetamol or other substances contained in the drug (allergy),
- Severe liver or kidney failure

Take MINAFEN carefully,

If;

- Anemia (anemia),
- If you have lung disease,
- Liver or kidney function is impaired,
- is using another drug containing paracetamol,
- If you have Gilbert syndrome, an inherited disease characterized by elevated liver enzymes and transient deafness,
- Redness of the skin, rash or a skin reaction.
- Hemolysis (destruction of red blood cells) can be seen rarely in patients with glucose 6 phosphate dehydrogenase deficiency, which is effective in blood sugar metabolism.

If new symptoms (symptoms) occur within 3 to 5 days, or if the pain and / or fever does not disappear, stop using paracetamol in your child and consult a doctor.

MINAFEN causes severe liver toxicity when taken in acute (short-term) high doses. In adults, chronic (prolonged and repeated) daily doses may cause liver damage.
Please consult your doctor if these warnings apply to you, even at any time in the past.

Taking MINAFEN with food and drink

Alcohol or alcohol-containing food, medicine, etc. may increase the risk of harmful effects to the liver.
Foods may reduce the absorption of paracetamol from the intestine.

Pregnancy
Consult your doctor or pharmacist before using this medication.
Although MINAFEN has not been reported to be harmful for use in pregnancy, it is still used with the advice of a physician during this period.
If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist before using this medication.

Taking MINAFEN at therapeutic doses by a nursing mother does not pose a risk to the baby. Paracetamol can be used with the recommendation of a physician during lactation as it passes to the milk even though it is a little.

Driving and using machines

It is not expected to have any effect on driving and machine driving.

Important information about some of the ingredients of MINAFEN

Due to the glycerin it contains, it may cause headache, nausea and diarrhea.
Patients with rare hereditary fructose intolerance problems should not use this medicine because of the sorbitol content.
This medicinal product contains less than 1 mmol (or 23 mg) of sodium per 5 ml. This should be considered for patients on a controlled sodium diet.

Other medicines and MINAFEN
The effect of MINAFEN may change when used in combination with certain medications.
Please tell your doctor if your child is taking the following medications:

- Drugs that delay gastric emptying (eg Propantelin, etc.)
- Drugs that accelerate gastric emptying (eg metoclopramide)
- Drugs that stimulate liver enzymes (eg some sleep medications, some drugs used in epilepsy)
- Chloramphenicol used as antibiotic
- Warfarin and coumarin-derived anticoagulants (drugs that prevent blood clotting)
- Zidovudine (a drug used in the treatment and prevention of HIV infections (AIDS) in children and adults)
- Domperidone (used in the treatment of nausea and vomiting)
- St John's wort / Hypericum perforatum
- Cholestyramine-containing drugs (used to treat high cholesterol)
- Drugs containing tropisetron and granisetron (used to prevent nausea and vomiting in patients receiving radiotherapy and / or chemotherapy).
- Use with other painkillers

If you are currently using or taking any prescription or over-the-counter medication, please inform your doctor or pharmacist.

3. HOW TO USE MINAFEN?

Instructions for proper use and dose / application frequency:

Infants under 3 months: A dose of 2.5 ml (half-scale) is appropriate for babies with post-vaccination fever after 2 months. It should not be used in infants under two months.
These doses may be repeated 4 times a day, leaving an interval of 4 hours or more after each dose.
Up to 60 mg / kg is used in divided doses of 10 to 15 mg / kg per day.
Do not use for more than 3 consecutive days without medical advice.
The daily dose of paracetamol should not exceed 2 grams due to liver toxicity.

Month	**Dose**	**Usage**
3-6 months	2.5 ml	Every 6 hours
6-24 months	5 ml	Every 6 hours
2-4 years	7.5 ml	Every 6 hours
4-6 years	10 ml	Every 6 hours

Method of administration

It is taken orally. The thick consistency of MINAFEN prevents spilling of the drug from the spoon and makes it easier to apply.

Different age groups:
Use in children: See Instructions for proper use and dosage / frequency of administration.

Elderly use: Tablet AF MINAFEN 'Tablet is recommended for adults who have difficulty swallowing tablets.

Special use cases:
It should be used with caution in mild to moderate liver or kidney failure.
Talk to your doctor or pharmacist if you have any indication that the effect of MINAFEN is too strong or too weak**.**

If you take more MINAFEN than you should

In the case of overdose wilt, loss of appetite, nausea and vomiting are the main symptoms, but in some cases may not show symptoms for hours. Therefore, in case of overdose or accidental medication, notify your doctor immediately or consult a hospital. In a short time (acute) high doses may cause liver damage. MINAFEN overdose should be treated immediately.
Talk to a doctor or pharmacist if you have used more than you should use from MINAFEN.

If you forget to take MINAFEN

Do not take double doses to compensate for forgotten doses.

If you stop taking MINAFEN

Take your medicine for as long as your doctor tells you to. It is not expected to show any adverse effects if used in accordance with the doctor's recommendation.

4. WHAT ARE THE POSSIBLE SIDE EFFECTS?

Like all medicines, people who are sensitive to substances contained in MINAFEN may have undesirable effects.

Side effects are classified as shown in the following categories:

Very common: It can be seen in at least one of 10 patients.

Common: Less than one in 10 patients, but more than one in 100 patients.

Uncommon: less than one in 100 patients, but more than one in 1,000 patients.

Rarely: Less than one in 1,000 patients may be seen.

Very rare: Less than one in 10,000 patients can be seen.

Unknown: Unable to estimate from the available data.

If one of the following occurs, stop using MINAFEN and notify your doctor IMMEDIATELY or contact the emergency department of your nearest hospital:

Skin rash, itching, eczema, allergic (hypersensitivity) edema, swelling of the face, tongue and throat (angioedema), diffuse discharge rashes (acute generalized exanthematous pustulosis), symptoms similar to scalding of the skin (toxic epidermal necolysis), hand, face and hypersensitivity to lace-like redness in the feet (erythema multiforme)
These are all very serious side effects. If you have one of these, you have serious allergies to MINAFEN. You may need urgent medical attention or hospitalization.

Very common side effects

- Above the upper limit of liver enzymes (ALT)

Common side effects

- Infection (inflammation-causing microbial disease)
- Headache
- Dizziness
- Drowsiness
- Paresthesia
- Upper respiratory tract infection
- Nausea
- Diarrhea
- Indigestion, digestive disorder (dyspepsia)
- Gas-related flatulence in the gastrointestinal tract
- Abdominal pain
- Constipation
- Vomiting
- Liver enzymes (ALT) 1.5 times the upper limit
- Face edema
- Post-extraction bleeding (bleeding after tooth extraction)

Uncommon side effects

- Impaired balance
- Bleeding in the stomach and intestine (gastrointestinal bleeding)
- Peripheral edema (edema in places such as hand and ankle)
- Post-tonsillectomy bleeding (bleeding after tonsillectomy)

Rare side effects

- Skin rash
- Hives (urticaria), itching
- Diffuse discharge rash (acute generalized exanthematous pustulosis)
- Symptoms similar to skin scald (toxic epidermal necrolysis)
- Hypersensitivity (erythema multiforme) that causes lace-like redness on hands, face and feet,
- Allergic edema
- Swelling of the face, tongue and throat (angioedema)
- Painful red or purplish rashes on the skin that usually begin with flu-like symptoms and subsequently result in the death of the upper layer of the skin (Stevens-Johnson syndrome).
- Spots (redness) and shaped lesions appearing with or without fever (eruption)

Very rare side effects

- Agranulocytosis (a dangerous leukopenia that may develop suddenly and frequently in the body (decrease in white blood cell count))
- Thrombocytopenia (decrease in the number of blood pulp (blood cells involved in clotting))
- Purpura (red bruises in the shape of a pinhead)

- Fire
- Asthenia (chronic fatigue)
- ron Bronchospasm (asthma-like symptoms that cause shortness of breath in the lung)
- Anaphylactic shock (swelling of hands, feet, face and lips or breathing especially in the throat)
- swelling
- Allergy test positive

Unknown side effects

- Nephrotoxic effects following therapeutic doses of paracetamol are not common. Papillary necrosis has been reported in long-term administration.

Inform your doctor or pharmacist if you encounter any side effects not mentioned in these instructions for use.

Reporting of side effects

In the event of any side effects, whether or not included in the instructions for use, talk to your doctor, pharmacist or nurse. Also located on the side effects www.titck.gov.t address you encounter "Drug Side Impact Statement" by clicking on the icon or 0800314 00 08 number of side effects by calling the notification line Turkey Pharmacovigilance Center (TÜFAM) 'What do you notice. By reporting the side effects that occur, you will contribute to gaining more information about the safety of the drug you are using.

5. STORAGE OF MINAFEN?

Keep MINAFEN out of the reach of children and in its packaging.
Store at room temperature below 25 ° C. Protect from light. Do not store in refrigerator.
MINAFEN is used without dilution.
Shake the bottle vigorously before each use.

Use in accordance with expiration dates.

Do not use MINAFEN after the expiry date indicated on the package.
Do not use MINAFEN if you notice defects in the product and / or packaging.
Unused solutions or wastes should be disposed of according to local procedures.
Do not dispose of expired or unused medicines! Hand over to the collection system determined by the Ministry of Environment and Urbanization.

Marketing Authorization Holder

Drogsan Pharmaceuticals San. ve Tic. Inc.
Oğuzlar Mah. 1370. Sok. 7/3
06520 Balgat-Ankara

Manufacturer:

Drogsan Pharmaceuticals San. ve Tic. Inc.
06760 Cubuk-Ankara

These operating instructions have been approved on 11/01/2018