PATIENT INFORMATION LEAFLET

PAROKAN 10 mg/ml Containing Solution For IV Infusion Used intravenous.

- ***Active ingredient:*** Each ml solution contains 10 mg of paracetamol.
- ***Excipients:*** Mannitol, cysteine hydrochloride monohydrate, disodium hydrogen phosphate dihydrate, sodium hydroxide, water for injection

Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.

- *Keep this PATIENT INFORMATION LEAFLET. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*
- *Follow these instructions exactly as written. Do not use* ***higher or lower*** *dose other than your recommended dose.*

The following headlines are included in this PATIENT INFORMATION LEAFLET:

1. What PAROKAN is and what it is used for?

• PAROKAN 10 mg/ml Containing Solution For IV Infusion contains 10 mg/ml paracetamol.

• PAROKAN 10 mg/ml Containing Solution For IV Infusion is clear and colorless or light yellow solution which is supplied in packs of 12 bottles.

• PAROKAN 10 mg/ml Containing Solution For IV Infusion is an analgesic (it relieves pain) and an antipyretic (it lowers fever).
• The 100 ml bottle is restricted to adults, adolescents and children weighing more than 33 kg.
• PAROKAN is indicated for the short-term treatment of moderate pain, especially following surgery and for the short-term treatment of fever, when administration by intravenous route is clinically justified by an urgent need to treat pain or hyperthermia and/or when other routes of administration are not possible.

2. Before you are given PAROKAN

DO NOT USE PAROKAN in the following cases:

If
;
• you are allergic (hypersensitive) to paracetamol, propacetamol (precursor of paracetamol) or to any of the other ingredients of PAROKAN (see list of excipients).
• if you suffer from a severe liver disease or have active liver disease.

Take SPECIAL CARE with PAROKAN in the following cases:

If
;
- You take another drug contains paracetamol,
- You suffer from liver impairment
- You suffer from severe kidney impairment
- You have anemia
- You have lack of enzyme called glucose 6 phosphate dehydrogenase (G6FD) (in this case your hemoglobin levels may decrease, red blood cells disrupt and hemolytic anemia occurs)
- You have ongoing alcohol consumption or you consume excessive alcohol (if you use 3 cups or more alcoholic drinks every day)
- You have anorexia, consume unbalanced and / or insufficient
- You are dehydrated

PAROKAN causes acute severe liver toxicity when administrated high doses. In adults, may cause liver injury in chronic daily high doses.

Skin redness, rash or skin reaction may occur in first use of Paracetamol or patients with already in use paracetamol history, in the first dose or repeated doses of use. In this case must be contacted with the doctor, discontinue of drug use and switched to an alternative treatment. People which observed skin reactions with other drugs containing acetaminophen, should not use this medication more or paracetamol. In this case may cause severe adverse reactions and death (see section 4. Possible side effects).

Please consult your doctor if any of these alerts even applies to you at any time in the past.

Taking PAROKAN with food and drinks
There is not any interaction with food and drink.

Pregnancy
Ask your doctor or pharmacist for advice before taking the medicine.

PAROKAN should not be used during pregnancy if isn't clearly necessary. Your doctor will inform you about risks of PAROKAN using during the pregnancy.

Please consult your doctor or pharmacist if you notice that you are pregnant during treatment.

Lactation
Ask your doctor or pharmacist for advice before taking the medicine.

If you are breastfeeding, you can use PAROKAN when doctor decides it is necessary.

Driving and using machines
If you feel uncomfortable after receiving PAROKAN, you should not use or drive machines. The ability to use and drive machines is not known to affected by PAROKAN.

Important information about some of the ingredients of PAROKAN
This medicinal product' each 100 ml contains less than a dose of 1 mmol of sodium. It is not expected to cause any side effects related to sodium in this dose.

Taking other medicines
If;
• You take probenecid an active substance for the treatment of gout- dose adjustment may be needed;
• You take salicylic acid derivate pain killers (Salicylamide, diflunisal)

• You take substances that induce enzymes in the liver that metabolize the drug (barbiturates, isoniazid, anticoagulants, zidovudine, amoxicillin +clavulonic acid and ethanol)
• You take drugs that use for treatment of convulsion (barbiturates, carbamazepine, phenytoin)
• You consume alcohol regularly
• You take anti-coagulants (coumarin or indandione derivates)
Inform your doctor. Dose adjustment might be necessary.

If you are currently using or have recently used any prescription or non-prescription medication, please give information to your doctor or pharmacist about these.

3. How PAROKAN will be given?

Your doctor will decide the dose of your medication, depending on the disease and will apply to you. At the end of this leaflet for more information you can read the statement prepared for situated and medical personnel.

Instructions for use and dose/ frequency of administration:

Switching to a suitable oral analgesic as soon as you are able to take oral is recommended. Single dose or recurrent doses could use to treatment of acute pain or fever.

Paracetamol solution is administered as intravenous infusion within 15 minutes.

The dose is adjusted according to the patient weight. Dosing recommendations are presented on the following table. Your doctor will make the appropriate dose adjustment.

Body weight of the patient	**Single dose**	**Maximum daily dose**

≤ 10 kg	**7.5 mg/kg** Paracetamol/ application (0.75 ml solution/kg)	- Four times daily maximum - Intervals of at least 4 hours must be given between the applications - **The maximum dosage of 30 mg/kg** must not be exceeded
> 10 kg and ≤ 33kg	**15 mg/kg** Paracetamol/ application (1.5 ml solution/kg)	- Four times daily maximum - Intervals of at least 4 hours must be given between the applications - **The maximum dosage of 60 mg/kg** must not be exceeded (maximum daily dosage **2g**.)
> 33kg and ≤ 50kg	**15 mg/kg** Paracetamol/ application (1.5 ml solution/kg)	- Four times daily maximum - Intervals of at least 4 hours must be given between the applications - **The maximum dosage of 60 mg/kg** must not be exceeded (maximum daily dosage **3g**)
> 50kg	**1 g** Paracetamol/ application (1 bottle of 100ml)	- Four times daily maximum - Intervals of at least 4 hours must be given between the applications - **The maximum dosage of 4 g** must not be exceeded

***Preterm newborns:** There are no available safety and effectiveness data for preterm newborns.

** **Maximum daily dosage**: As shown in the table above, the maximum daily dosage relates to patients that do not use any other products. All the paracetamol dosages administered through all the routes (oral, rectal, intravenous, etc.) must be taken into consideration.

Route of administration and method:
Used intravenous.

Paracetamol solution is administered as intravenous infusion within 15 minutes.

Different age groups:
Usage in children and adolescent (under 18 years old)

PAROKAN 100 ml bottle is restricted to adolescents and children weighing more than 33 kg.

Usage in elderly (above 65 years of age):
Dose adjustment is not required in elderly patients.

Conditions of special use:
Renal failure
In patients with serious renal failure (creatinine clearance ≤30 ml/min), intervals of 6 hours between each administration is recommended.

Liver failure
In patients with chronic or active liver diseases, particularly in those with hepatocellular insufficiency, chronic alcoholism, chronic malnutrition (low liver glutathione levels) and dehydration, the daily 3 mg/day dosage must not be exceeded.

The daily paracetamol dosage must not exceed 2 g in individuals taking alcohol regularly because of hepatotoxicity risk.

If you have an impression that the effect of PAROKAN is very strong or weak, please tell your doctor or pharmacist.

If you use more PAROKAN than you should:
Toxicity is possible if 7.5 g or more is taken as a single dosage in adults and with 140 mg/kg in children.

If you use more PAROKAN than you should; nausea, vomiting, anorexia, abdominal pain may be seen and you may look pale.
It is recommended to monitorize renal functions except emergency measures.

If you use more PAROKAN than you should, talk to a doctor or pharmacist.

If you forget to use PAROKAN:
Do not take a double dose to compensate forgotten dose.

If PAROKAN treatment stopped, effects may occur:
Unknown.

4. Possible side effects
Like all other medicines, PAROKAN may cause side effects in patients with hypersensitivity to any component content.

If one of following occurs, stop using PAROKAN and tell your doctor immediately or consult nearest emergency department of hospital

- swelling on face and throat due to allergy (angioneurotic edema)
- unexplained redness, swelling, papula on skin or skin loss
- hypersensitivity
- very severe body's response to certain allergy-inducing substances, immediate hypersensitivity (anaphylaxis)
- shock due to peracute hypersensitivity response
- Some disorders related to the liver (liver failure, liver inflammation, changes in enzyme levels)

All of adverse effects are very serious.

If you have one of these, you are allergic to PAROKAN. You
may need urgent medical attention or admitted to hospital.

These very serious adverse effects are very rare.

The frequency of side effects is classified into the following categories:
Very common in more than 1 in 10 patients
Common in more than 1 in 100 patients, but less than 1 in 10 patients
Uncommon in more than 1 in 1,000 patients, but less than 1 in 100 patients
Rare in more than 1 in 10,000 patients, but less than 1 in 1,000 patients
Very rare in less than 1 in 10,000 patients, including isolated reports

Rare:

- Decrease on tension
- Increase on liver transaminase enzymes
- Increase on heart beat
- Weakness
- Malesia

Very rare:

- Thrombocytopenia
- Hypersensitivity reaction

Post marketing effects:

Not known:

- Thrombocytopenia
- Increase on heart beat
- Nausea, vomiting
- Reaction on application side

Rare:

- Redness on skin
- Rash, itching
- Redness on face
- Urticaria
- Allergic edema
- Angioedema
- Acute generalised exanthematous pustulosis,
- Erythema multiform, Stevens-Johnson Syndrome,
- Toxic epidermal necrolysis

Reporting of side effects

If you get any side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to your doctor or pharmacist. You can also report side effects directly to your country's related health authority. By reporting side effects, you can help provide more information on the safety of this medicine.

If you encounter with any side effects that are not mentioned in this leaflet, please inform your doctor or pharmacist.

5. How to store PAROKAN

Keep PAROKAN out of the reach and sight of children and store in the original package.

Store below 30°C. Do not store on refrigerator or do not freeze.

Use in accordance with the expiration date.
Do not use PAROKAN after the expiration date which is stated on the package. Expiration date is last day of month that stated 'expiration date'.

If you notice any disorders in product and/or package, do not use PAROKAN. Before the application, the product should be made visually for particulate matter and discoloration control. If you notice any particulate matter or if you notice discoloration; do not use PAROKAN.

Marketing Authorisation Holder: Magna Pharma İlaç A.Ş.
Acarlar Mah. 74. Sok.
Acarkent Sitesi No:17/1
Beykoz / İSTANBUL

Manufacturing site Osel İlaç San. Tic. A.Ş.
Akbaba Mah. Maraş Cad. No:52
Beykoz / İSTANBUL

This leaflet was approved in 26/10/2017

THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS.

Method of administration:

Take care when prescribing and administering PAROKAN to avoid dosing errors due to confusion between milligram (mg) and milliliter (mL), which could result in accidental overdose and death. Take care to ensure the proper dose is communicated and dispensed. When writing prescriptions, include both the total dose in mg and the total dose in volume. Take care to ensure the dose is measured and administered accurately.
Paracetamol solution is administered as intravenous infusion within 15 minutes.
Since the 100 ml (1000 mg) bottle can cause dosage errors (administration of overdose); it must not be used as a whole for patients under 50 kg.
The drug must be drawn from the bottle to administer dosages less than 100 ml.
Infusion must be made without hanging the bottle for patients with body weights < 10 kg.
Pediatric (for children) dosages up to 60 ml must be administered with a syringe within a period of 15 minutes.

With the purpose of avoiding dosage errors in newborns and infants (≤ 10 kg) and not to confuse mg with ml, it is recommended that the volume to be administered in milliliters (mL). The PAROKAN volume (10 mg/ml) administered to this weight group must never exceed 7.5 ml per dosage. Very little volumes will be required for the newborns and infants (≤ 10 kg).

To measure the dosage with the required volume based on the body weight of the child, 5-ml or 10-ml syringes must be used.

PAROKAN can also be administered by diluting for pediatric population. However, only 0.9% sodium chloride or 5% dextrose solutions can be used up to 1: 10 (1 aliquot of paracetamol within 9 aliquots of diluent). The diluted solution must be used within one hour (including the infusion time) after preparation. The diluted solution must be used within one hour following preparation (infusion time included).

The drug must be drawn from the bottle to administer dosages less than 100 ml.
Infusion must be made without hanging the bottle for patients with body weights < 10 kg.
Pediatric dosages up to 60 ml must be administered with a syringe within a period of 15 minutes.

Like in any other drug available within glass bottles, close follow-up particularly after infusion is recommended. The requirement of close follow-up is particularly important as regards the air embolism when infusion is made through the central venous route.

Before the application, the product should be made visually for particulate matter and discoloration control. If you notice any particulate matter or if you notice discoloration; do not use PAROKAN. It is used only. Unused solution should be discharged.

Should be used immediately after the product is switched on, as long as open method does not eliminate the risk of microbial contamination. If not used immediately, the user is responsible for the storage time and conditions during use.

Unused products or waste materials must be disposal according to “Medical Waste Control Regulation” and “Packaging and Packaging Waste Control Regulation”.