Patient leaflet in accordance with the pharmacists' regulations (preparations) 1986

This medicine is to be supplied upon physician's prescription only

Sedural (new formulation)

dragée (coated tablets)

This format of this leaflet was determined by the ministry of Health and its content was checked and approved it in April 2013

Active Ingredients - each tablet contains
Phenazopyridine hydrochloride 100 mg
Excipients agents: See section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains summary information about this medicine. If you have any further questions, refer to the physician or pharmacist.

This medicine has been prescribed for treating your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar.

The medicine is usually not intended for children and infants under the age of 12.

1. What is this medicine intended for?

The medication is intended for relief of pain, burning and discomfort in the urinary tract.

Therapeutic group: Analgesics for the urinary tract.

2. Before using this medicine

Do not use this medicine if:

- You are allergic to the active agent Phenazopyridine or to any of the other ingredients that this medicine contains.
- You have known G6PD deficiency (sensitivity to fava beans).
- You suffer from hepatic or renal insufficiency.
- You suffer from acute liver inflammation (hepatitis).
- You suffer from renal pelvis and kidney (pyelonephritis) of pregnancy.

Do not use this medicine without consulting a doctor before starting treatment you suffer or have suffered in the past from impaired liver or kidney function.

Special warnings related to the use of the medicine

- If you are sensitive / any food or medicine, inform your doctor before taking this medicine.
- For patients wearing soft contact lenses – it is recommended to refrain from wearing contact lenses due to the risk of damage to the lenses.
- For diabetes patients – use of this medicine may lead to incorrect results in urine tests for glucose/ketones.
- Inform the physician of taking this drug before performing any medical test.
- The medicine may delay the growth of bacteria in urinary culture.
- This medicine may cause changes in the color of urine (red-orange) and underwear stains.
- Use of this medicine as a urinary tract analgesic is not a substitute for physician's consultation and examination to identify the cause of pain.
- The duration of treatment of urinary tract infection with this medicine should not exceed two days, since there is no proof that the combination of Phenazopyridine (Sedural, new formulation) with an antibiotics agent is more effective than an antibiotics agent alone after two days.
- Yellowish shade of the skin or the eye sclera (the white of the eye) may indicate accumulation of this medicine due to abnormal renal secretion; therefore, in such case, treatment discontinuation is recommended.
- Use of this medicine may cause renal insufficiency in elderly patients.

If you are taking or have recently taken other medicines including non-prescription medicines and dietary supplement, tell the physician or the pharmacist.

Use of the medicine and food

Swallow the medicine with water, with or after a meal.

Use of the medicine and alcohol consumption

Do not drink wine or any other alcoholic beverages while using the medicine.

Pregnancy and breastfeeding

Do not use the medicine without consulting a physician prior to beginning treatment if you are pregnant, plan to become pregnant or breastfeeding.

Driving and using machines

Do not drive or use machines while using the medicine until you know how the medicine affects you.

Important information about some ingredients of the medicine Sedural (new formulation)

This medicine contains dyes and preservatives. The medicine may cause allergic reactions. This medicine contains sucrose. Do not use the medicine without consulting a physician prior to beginning treatment if you have intolerance to fava beans (G6PD deficiency).

3. How to use the medicine?

Always use according to the physician's instructions. The dosage and treatment will be determined only by the physician. You should check with the physician or the pharmacist if you are unsure.

Do not exceed the recommended dose. This medicine is taken at regular intervals as determined by your doctor.

This medicine is usually not intended for children and infants under the age of 12.

When used in combination with antibacterial agents for the treatment of urinary tract infection, the duration of Phenazopyridine (Sedural, new formulation) use should not exceed two days.

Swallow the medicine with water, with or after a meal. Do not take this medicine with alcohol.

Do not chew! Do not split or crush the tablet.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room and bring the medicine package with you.

Possible symptoms of an overdose: methemoglobinemia (including: pale, light grayish or blue skin, lips or nails; shortness of breath; fatigue; confusion; headache; dizziness; rapid heart rate (tachycardia)), hemolytic anemia, hepatic and renal toxicity.

If you forgot to take the medicine at the scheduled time, Take the dose as soon as you remember but never take two doses together. Take the next dose at the usual time and consult the physician.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

Persist with the treatment as recommended by the physician. If you have any questions on use of this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, use of **Sedural (new formulation)** may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

This medicine may cause changes in the color of urine. These changes are not a reason for concern.

Consult a physician if you experience:

- Headache.
- Abdominal pain.
- Dizziness.
- Indigestion.
- Nausea, vomiting, diarrhea.

Consult a physician immediately if you experience:

- Yellowing of the skin/eyes.
- Fever.
- Vision impairments.
- Blue or purple color of the skin.
- Swelling of the face, fingers and legs.
- Confusion.
- Cramps.
- Difficulties breathing.
- Rash.
- Reduced urine output.
- Fatigue/weakness.
- Methemoglobinemia or hemolytic anemia.

If any of the side effects gets worse, or when you suffer from a side effect not mentioned in the leaflet, or if you feel any change in your general feeling, you should consult the physician.

Side effects and drug interactions in children: The parents should report to the attending physician on any side effects and any additional medicine given to the child!

See above side effects and drug interactions mentioned special.

5. How to store the drug?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store in a dry and dark place, below 25˚C.

6. Additional information

In addition to the active ingredient the medicine also contains: Avicel PH 102, Sodium Starch Glycolate (Primojel), PVP K 30, Starch 1500, Gelatin, AC-DI-SOL, Magnesium Stearate.

Coating:

Acacia, Carnauba Wax, Color Ponceau 4R Lake 11%, D&C Yellow no. 10 15% Aluminium Lake, FD&C Blue no. 2 Aluminium Lake 12%, FD&C Red no. 3 Aluminium Lake, Liquid Glucose=glucose syrup, Methylparaben, Monobasic Potassium Phosphate, Polyethylene Glycol, Providone Precipitated Calcium Carbonate, Propylparaben, Sodium benzoate, Sucrose, Talc, Titanium Oxide, Gelatin, Ethanol 95%.

What does the medicine look like and what is the content of the package: The medicine is marketed in blisters of 10 tablets per blister, 3 blisters in each package.

License holder and manufacturer: Rekah Pharmaceutical Industry Ltd., 30 Hamelacha St. Holon, Israel

This leaflet was checked and approved by the Ministry of Health in: 04/2013

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 137-47-20755-00

For simplicity and easier to read, this leaflet is formulated male language, however, the medicines is intended for members of both sex.