

## **Package leaflet: information for the user**

### **Solpadeine Soluble 500 mg/8 mg/30 mg effervescent tablets** paracetamol, codeine phosphate hemihydrate, caffeine

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

#### **What is in this leaflet**

1. What Solpadeine Soluble is and what it is used for
2. What you need to know before you use Solpadeine Soluble
3. How to use Solpadeine Soluble tablets
4. Possible side effects
5. How to store Solpadeine Soluble tablets
6. Contents of the pack and other information

#### **1. What Solpadeine Soluble is and what it is used for**

Solpadeine Soluble contains three active substances: paracetamol, codeine phosphate hemihydrate and caffeine.

Paracetamol is an analgesic and anti-inflammatory medicine.

The anti-inflammatory effect is based on controlling the thermoregulatory centre of the hypothalamus; body temperature drops due to increased peripheral blood flow and sweating.

Codeine phosphate has a moderate analgesic and mild antitussive effect. Codeine may be used in children older than 12 years for short-term treatment of moderate pain that is not relieved by other analgesics, such as paracetamol or ibuprofen.

This medicine contains codeine. Codeine is in the group of medicines called opioid analgesics, which reduce pain. It is used separately or in combination with other analgesics, such as paracetamol.

Caffeine is regarded as a component that increases the analgesic effect of a medicine due to its stimulating effect in the central nervous system, which helps relieve pain-related depression. Solpadeine Soluble tablets are used for moderate pain.

#### **2. What you need to know before you use Solpadeine Soluble**

##### **Do not use Solpadeine Soluble tablets**

- if you are allergic to the active substances (paracetamol, codeine and caffeine), other opioids or any of the other ingredients of this medicine (listed in section 6);
- together with other medicines that contain paracetamol and/or codeine;
- if you have asthma and experience asthma attacks or difficulties breathing;
- to relieve pain in children and adolescents (0–18 years of age) following a tonsillectomy and/or adenoidectomy performed due to the acute obstructive sleep apnoea syndrome;
- if you are aware that your body breaks codeine down into morphine very quickly;
- if you are pregnant or breast-feeding;

- if you are younger than 12 years of age;
- if you have had a head injury or a condition related to increased intracranial pressure;
- if you have chronic constipation
- if you have recently had a biliary duct surgery
- if you are taking or have taken in the last 14 days medicines called MAO inhibitors (MAOIs).

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Solpadeine Soluble:

- if you have kidney or liver problems (including Gilbert's syndrome or alcohol-related liver disease)
- if you have an intolerance to some sugars or glucose-6-phosphate dehydrogenase deficiency
- if you have low blood pressure
- if you have a problem with your thyroid gland
- if you have haemolytic anemia
- if you suffer from malnutrition or dehydration
- if you have problems with your gut, including bowel obstruction or acute abdominal disease
- if you have had your gallbladder removed
- if you have glutathione deficiency
- if you are taking antidepressants
- in case of chronic alcoholism
- if you are on a low sodium diet. Each tablet contains sodium (427 mg)
- the elderly, adults and adolescents weighing less than 50 kg.
- if you are or have ever been addicted to opioids, alcohol, prescription drugs or illegal substances. Regular long-term use of codeine (the active substance) can lead to addiction and misuse, which can lead to overdose and / or death. Do not take this medicine for longer than necessary. Do not pass this medicine on to others.

Talk to your doctor if symptoms persist for more than 3 days or worsen.

Prolonged use of any type of painkiller for headaches may aggravate it. If this situation occurs or is suspected, a doctor should be consulted.

This medicine should be taken in the lowest possible dose for the shortest duration of time required to relieve the symptoms. Taking this medicine regularly for a long period may lead to the development of dependency.

Avoid the excessive intake of products, which contain caffeine (e.g. coffee, tea, and some canned drinks).

Enzymes in the liver transform codeine into morphine. Morphine is an analgesic substance. In some people, the enzyme has been modified and may have a different effect on people. In some people, morphine is not produced or is produced in very small quantities and the analgesic effect is insufficient. In other people, severe side effects are more likely, as the body produces morphine in large quantities. If you observe any of the following side effects, discontinue taking this medicine and seek immediate medical attention: slow or shallow breathing, confusion, drowsiness, small pupils, nausea or vomiting, constipation, lack of appetite.

### **Children and adolescents**

#### Use in children and adolescents following a surgery

In children and adolescents, codeine may not be used to relieve pain following a tonsillectomy and/or adenoidectomy performed due to the acute obstructive sleep apnoea syndrome.

#### Use in children with respiratory problems

Codeine is not recommended to be used in children with respiratory problems, as symptoms of morphine poisoning may be more severe.

### **Other medicines and Solpadeine Soluble**

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

Consult your doctor before taking Solpadeine Soluble tablets if you are taking:

- metoclopramide or domperidone (medicines used to treat nausea and vomiting);
- cholestyramine (a medicine that reduces lipid levels in the blood)
- probenecid (gout medicine)
- medicines that make you drowsy, such as sedatives, tranquilisers, tricyclic antidepressants, phenothiazines, or alcohol;
- medicines called decongestants (which reduce nasal mucosal swelling)
- medicines called the MAOIs (monoamine oxidase inhibitors) - Solpadeine Soluble should not be used with these medicines;
- medicines that thin the blood, such as warfarin;
- flucloxacillin (antibiotic), due to the serious risk of blood and fluid disorders (high anion gap metabolic acidosis) which must be treated urgently and may occur especially if there is severe kidney damage, sepsis (when bacteria and their toxins circulate in the blood, causing organ failure damage), malnutrition, chronic alcoholism, and when maximum daily doses of paracetamol are used.

Concomitant use of Solpadeine Soluble with sedatives (eg benzodiazepines) or similar drugs increases the risk of somnolence, respiratory distress and coma and can be life-threatening. Therefore, concomitant use should only be considered on the advice of a physician if no other treatment is available. However, if your doctor decides that you need Solpadeine Soluble at the same time as sedatives, the doses and duration of use prescribed by your doctor must be followed very closely. Tell your doctor about any sedatives you are taking and follow your doctor's instructions exactly.

Tell your loved ones about the above symptoms so that they are aware of their possibility. Contact your doctor immediately if you experience such symptoms.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice.

Do not use Solpadeine Soluble tablets during pregnancy and breast-feeding.

Codeine and morphine are excreted in breast milk. Medicines, which contain codeine, may harm your child if taken while breast-feeding.

### **Driving and using machines**

The medicine may cause dizziness and drowsiness. If you experience these symptoms, avoid driving and using machines.

### **Solpadeine Soluble contains sodium and sorbitol**

This medicine contains 427 mg of sodium (the main component of common salt) per tablet. This is 21% of the maximum recommended daily amount of sodium for an adult.

This medicine contains 50 mg of sorbitol (E420) per tablet. If you have been told by your doctor that you have an intolerance to some sugars, or a hereditary fructose intolerance (HFI), a rare genetic disorder that prevents fructose from breaking down in your body, you should talk to your doctor before taking this medicine.

## **3. How to use Solpadeine Soluble tablets**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

### **Adults**

If needed, 1 to 2 tablets dissolved in at least half a glass of water up to 4 times a day, every 4 to 6 hours. Do not exceed 4 doses (8 tablets) in 24 hours.

### **Adolescents aged 16 to 18 years**

If needed, 1 to 2 tablets dissolved in at least half a glass of water up to 4 times a day, every 6 hours. Do not exceed 4 doses (8 tablets) in 24 hours.

### **Adolescents aged 12... 15 years**

If needed, 1 tablet dissolved in at least half a glass of water up to 4 times a day, every 6 hours. Do not exceed 4 doses (4 tablets) in 24 hours.

### **Children under 12 years of age**

This medicine should not be taken by children under 12 years of age because of the risk of severe breathing problems.

Do not exceed the prescribed daily dose or the dose prescribed by your doctor due to the risk of liver damage.

If the pain does not improve within 3 days, the condition worsens or new symptoms develop, stop treatment and talk to your doctor.

Do not take Solpadeine tablets with medicines containing paracetamol or codeine.

### **If you take more Solpadeine Soluble than you should**

If you have taken more Solpadeine Soluble tablets than prescribed, contact your doctor immediately, as there is a risk of developing liver failure and breathing problems.

If you have exceeded the recommended dose, contact your doctor immediately even if you do not feel worse.

If you have any further questions on the use of this medicine, consult your doctor or pharmacist.

## **4. Possible side effects**

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

While taking this medicine, you may experience:

- constipation, nausea, vomiting
- changes in your blood picture
- drowsiness, dizziness
- exacerbation of headaches and drug dependence with prolonged use
- difficulty breathing in people who have had a hypersensitivity to acetylsalicylic acid (aspirin) or similar medicines

Serious skin reactions have been reported very rarely.

### **Stop taking this medicine and contact your doctor immediately:**

- if you have recently had a gall bladder removal surgery and feel acute stomach pain, nausea, and you are vomiting;
- if after taking Solpadeine Soluble tablets you experience an allergic reaction in the form of a skin rash, itching; sometimes breathing problems or swelling of the lips, tongue, throat or face may occur;
- if after taking Solpadeine Soluble tablets you experience a skin

- reaction (skin rash, itching, sweating, purpura, hives, angioedema, peeling, flaking or sores in the mouth);
- if you have previously had breathing problems when taking acetylsalicylic acid or other non-steroidal anti-inflammatory substances and if you are experiencing the same symptoms when taking Solpadeine Soluble tablets;
- if, after taking Solpadeine Soluble tablets, you experience unexplained bruising or bleeding.

Excessive drinking of tea or coffee during the use of Solpadeine Soluble may cause irritation and tension.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [www.ravimiamet.ee](http://www.ravimiamet.ee). By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. How to store Solpadeine Soluble tablets**

Keep this medicine out of the sight and reach of children!

Do not store at a temperature higher than 25 °C.

Do not use this medicine after the expiry date which is stated on the carton.

The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Solpadeine Soluble contains**

- The active substances are paracetamol, codeine phosphate hemihydrate and caffeine. Every tablet contains 500 mg of paracetamol, 8 mg of codeine phosphate hemihydrate and 30 mg of caffeine.
- The other ingredients are sodium bicarbonate, sorbitol, sodium saccharin, sodium lauryl sulphate, citric acid, sodium carbonate, anhydrous sodium carbonate, povidone, dimethicone and purified water.

### **What Solpadeine Soluble looks like and contents of the pack**

White, round, bevelled-edge and scored tablets.

The PPFP, or surlyn laminate strip in a carton, contains 4, 8, 12, 24, or 60 effervescent tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

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### **Manufacturers**

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