Package leaflet: Information for the user

Therimin Skogsbär 500 mg Powder for Oral Solution

paracetamol

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

Always take 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.
- If pain persists for more than 5 days or fever lasts for more than 3 days, or worsen, you should contact a doctor.

What is in this leaflet

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2. What you need to know before you take Therimin Skogsbär
3. How to take Therimin Skogsbär
4. Possible side effects
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1. What Therimin Skogsbär is and what it is used for

Therimin Skogsbär is a powder for a hot liquid medicine available in sachets. It contains the active ingredient paracetamol which is an analgesic (pain killer) and fever reducer (decreases body temperature).

Therimin Skogsbär is used for the short-term treatment of mild to moderate pain and fever associated with colds and flu, headache, muscles and joints pains, toothache and menstrual pain.

This medicine is recommended in adults and adolescents aged 12 years and above.

It can be used by people with a sensitive stomach.

If pain persists for more than 5 days or fever lasts for more than 3 days, or worsen, you should contact a doctor.

2. What you need to know before you take Therimin Skogsbär

Do not take Therimin Skogsbär if you

- are allergic to paracetamol or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Do not exceed the daily dose stated in section 3. Higher doses than recommended do not give better pain relief, instead it can result in very severe liver damage. **You must contact a doctor straight away if you have taken an overdose, even if you feel well.** The symptoms of liver damage are normally visible within a few days.

Do not take any other paracetamol-containing products at the same time as there is a risk of exceeding the maximum daily dose of paracetamol. Check the ingredients of other medicines before taking them when you are using Therimin Skogsbär.

Do not take this medicine unless prescribed by your doctor if you have a drinking problem or liver damage. Do not use Therimin Skogsbär together with alcohol. The effect of alcohol will not be enhanced by the addition of paracetamol, but alcohol may increase the toxic effects of paracetamol on your liver.

Talk to your doctor or pharmacist before taking this medicine if you

- are suffering from kidney problems,
- are suffering from liver problems including liver problems due to excessive alcohol consumption
- have Gilbert's syndrome (mild jaundice),
- suffer from glucose-6-phosphatedehydrogenase deficiency (enzyme deficiency),
- have haemolytic anaemia (abnormal breakdown of red blood cells),
- are suffering from dehydration or chronic malnutrition,
- are taking other paracetamol containing medicines,
- If you have asthma and are sensitive to aspirin.

You may need to avoid using this product altogether or limit the amount of paracetamol that you take.

During treatment with Therimin Skogsbär, tell your doctor straight away if:

- you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Children

Do not give this medicine to children under 12 years of age or under 41 kg body weight.

Other medicines and Therimin Skogsbär

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

In particular, tell your doctor before using Therimin Skogsbär if you are taking:

- Medicines for thinning the blood (anticoagulants), such as warfarin or other coumarins.
- Paracetamol containing medicines (see "Section 2 - Warnings and precautions).
- Medicines for nausea and vomiting, such as metoclopramide or domperidone.
- Medicines that slow gastric emptying, such as exenatid.
- Cholestyramine, used to lower blood cholesterol. There should be an interval of at least one hour between cholestyramine and Therimin Skogsbär.
- Medicines used to treat tuberculosis (rifampicin and isoniazid), for bacterial infections (chloramphenicol).
- Probenecid used to treat gout.
- Medicines used to treat seizures, such as phenytoin, phenobarbital and carbamazepine.
- St. John's wort (ingredient in certain herbal medicines).

  flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Therimin Skogsbär with food, drink and alcohol

Do not drink **alcohol** while using this medicine.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. If necessary, this medicine can be used during pregnancy. You should use the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible. Contact your doctor/midwife if the pain and/or fever are not reduced or if you need to take the medicine more often.

Paracetamol passes in small amounts into breast milk. This medicine may nevertheless be taken if you are breast-feeding. Do not exceed the daily dose and treatment duration recommended in this leaflet.

Driving and using machines

Therimin Skogsbär does not affect the ability to drive or use machines.

Important information about some of the ingredients in this medicine

Therimin Skogsbär contains:

- **aspartame (E951)** 32 mg per sachet, a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.
- **sodium** (main component of cooking/table salt) 38 mg per sachet: This is equivalent to 1.9% of the recommended maximum daily dietary intake of sodium for an adult.
- **sucrose** 4.9 g per sachet. If you have been told by your doctor that you have intolerance to some sugars, ask your doctor before use. This should also be taken into account if you suffer from diabetes.
- **lecithin soya (E322)**. If you are allergic to peanut or soya, do not use this medicinal product.

3. How to take Therimin Skogsbär

Always take 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.

Do not exceed the stated dose. Use the smallest dose that you need to treat your symptoms and for the shortest period of time necessary

The recommended dose is:

Adults

Take 1 to 2 sachets (500 to 1000 mg) every 4 to 6 hours as needed, up to a maximum of four times a day.

Usually one sachet per dose is sufficient. Do not take more than 6 sachets (3000 mg) in 24 hours.

Leave an interval of 4 to 6 hours between two doses

Children and adolescents

- **Children below 12 years of age or weighing less than 41 kg:** do not give to children under 12 years of age or weighing less than 41 kg.
- **Adolescents of 12 to 15 years and weighing 41 to 50 kg:**

One sachet per dose, every four to six hours as needed, up to a maximum of four times a day.
Do not use more than 4 sachets (2000 mg) in 24 hours.
Leave an interval of 4 to 6 hours between two doses.

- **Adolescents of 16 to 18 years and weighing more than 50 kg:** as adults.

The total dose of paracetamol should not exceed 60 mg/kg/day for adolescent and adults weighing less than 50 kg.

Patients with hepatic and renal disease

In patients with impaired liver or kidney function or with Gilbert's syndrome, the dose must be reduced or the dosing interval prolonged. Ask your doctor for advice before using this medicine.

How to take Therimin Skogsbär

The contents of 1 or 2 sachets should be dissolved in a standard mug of hot, but not boiling, water (approximately 250 ml). When 2 sachets are used, more water can be added according to taste. Drink when cooled to an acceptable temperature.

After dissolution of the powder in hot water, the liquid has a hazy yellow to greenish yellow colour.

How long to take Therimin Skogsbär

If pain persists for more than 5 days or fever lasts for more than 3 days, or worsen, you should contact a doctor.

If you take more Therimin Skogsbär than you should

In the event of an overdose, or accidental intake, contact a doctor, hospital or a Poison Control Centre immediately. Prompt medical attention is critical even if you feel well, because of the risk of serious liver damage.

If you forget to take Therimin Skogsbär

If you forget a dose, take it as soon as you remember unless it is almost time for your next dose. Then continue treatment as recommended. Always leave an interval of at least 4 hours between two doses. Never take a double dose to make up for a forgotten dose.

4 Possible side effects

Like all medicines, Therimin Skogsbär can cause side effects, although not everybody gets them.

STOP taking this medicine and tell a doctor or pharmacist immediately if you experience:

- allergic reaction including shortness of breath, swelling of the face, mouth, tongue or throat.
- skin rash (including hives, itching), redness of the skin.
- skin peeling, blisters, sores, mouth ulcers.
- blood problems, including unusual bleeding or bruising.
- any change in the appearance or amount of urine, including cloudy urine, blood in urine, inability to urinate. These are signs of kidney problems.
- yellowing of the skin or eyes (jaundice). These are signs of liver problems. Abnormal liver laboratory tests may also be observed.
- breathing problems if you are sensitive to aspirin or other non-steroidal anti-inflammatories and experience a similar reaction with this product.

The above side effects are rare (may affect up to 1 in 1,000 people) or very rare (may affect up to 1 in 10,000 people).
Very rare cases of serious skin reactions have been reported.

Frequency not known (frequency cannot be estimated from the available data):

A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

Other side effects may occur in rare cases (may affect up to 1 in 1,000 people). If you experience any of the following, tell your doctor:

- nausea, stomach ache, vomiting, diarrhoea.
- depression, confusion, sensing unreal things (hallucinations).
- tremor, headache, dizziness, vertigo, nervousness, confusion.
- abnormal vision.
- abnormal accumulation of fluid under the skin (oedema).
- dizziness, feeling of general discomfort or uneasiness (malaise), fever, drowsiness.
- Sweating

The following side effect may also occur in very rare cases (may affect up to 1 in 10,000 people). If you experience it, tell your doctor:

- low levels of glucose in the blood (hypoglycemia).

Reporting of side effects

If you get any 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 directly via the national reporting

system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Therimin Skogsbär

Keep this medicine out of the sight and reach of children and adolescents.

Do not use this medicine after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not use the product if you notice any visible sign of deterioration.

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 to protect the environment.

6. Contents of the pack and other information

What Therimin Skogsbär contains

The active ingredient is paracetamol 500 mg per sachet.

The other ingredient(s) are:

ascorbic acid (Vitamin C), acesulfame potassium, aspartame (E951), calcium phosphate, citric acid, maltodextrin, silica colloidal hydrated, sodium citrate, sucrose, quinoline yellow (E104), blueberry flavour (contains lecithin soya), raspberry flavour (contains lecithin soya), cranberry flavour (contains lecithin soya), menthol flavour (contains lecithin soya), green tea flavour (contains lecithin soya). (See end of section 2 for further information on some of the ingredients).

What Therimin Skogsbär looks like and contents of the pack

Therimin Skogsbär is a white to off-white, pale yellow granular powder with brown granules packed in individual sachets.

Therimin Skogsbär is available in packs of 6, 8, 10 or 12 sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

{Name and address}
<{tel}>
<{fax}>
<{e-mail}>

This medicinal product is authorised in the Member States of the EEA under the following names:

Finland	Theramin Metsämarja 500 mg jauhe oraaliliuosta varten (to be confirmed)
Iceland	Theramin Wildberries (to be confirmed)
Norway	Theramin pulver i dosepose med skogsbærsmak (to be confirmed)
Poland	Theraflu Grip Owoce leśne
Sweden	Thermin Skogsbär

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