

PACKAGE LEAFLET: INFORMATION FOR THE USER

Grippostad Day Capsules

Active substances: paracetamol, caffeine, phenylephrine hydrochloride.

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Grippostad Day carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Grippostad Day is and what it is used for
2. Before you take Grippostad Day
3. How to take Grippostad Day
4. Possible side effects
5. How to store Grippostad Day
6. Further information

1. What Grippostad Day is and what it is used for

Grippostad Day contains three drugs to help treat your symptoms (active ingredients):

- Paracetamol, which is an analgesic (pain killer) and antipyretic (it reduces body temperature when you have a fever)
- Phenylephrine, which is a type of drug known as a sympathomimetic. This works as a decongestant by unblocking the passages in and around your nose. This helps you to breathe more easily.
- Caffeine, which acts to further help the effectiveness of paracetamol.

Grippostad Day is used to relieve the symptoms of colds and influenza (flu) including fever, aches and pains, sore throat and nasal congestion.

This medicine is for use in adults and children aged 12 years and over.

2. Before you take Grippostad Day

DO NOT take Grippostad Day

- If you are **allergic** (hypersensitive) to paracetamol, caffeine, phenylephrine

hydrochloride, or any of the other ingredients of Grippostad Day (see section 6. "Further information" at the end of this leaflet)

- If you have a rare hereditary disease known as **glucose-6-phosphate dehydrogenase (G6PD) deficiency**. G6PD deficiency is a shortage of an enzyme and can lead to anaemia (a shortage of red blood cells).
- **If you have a tumour of the adrenal glands** called a phaeochromocytoma. The adrenal glands are triangle-shaped and located on top of your kidneys.
- If you have **liver problems**
- If you have **severe kidney problems**
- If you have **high blood pressure**
- If you have a **thyroid gland that is too active**
- If you have **diabetes**
- If you have **heart disease**
- If you have **raised pressure in the eye (glaucoma)**
- If you are taking drugs known as **beta blockers**
- If you are taking drugs for depression known as **tricyclic antidepressants**
- If you are taking or have taken drugs for depression known as **monoamine oxidase inhibitors (MAOIs)** in the last two weeks.

Take special care with Grippostad Day

- If you have an **enlarged prostate gland**. Symptoms of an enlarged prostate gland include difficulty urinating, painful urination, or urinating more often.
- If you have **Raynaud's phenomenon** (discolouration of the fingers and toes caused by poor circulation)
- If you have heart or **circulation problems**
- If you are an **alcoholic**

You should not use Grippostad Day if you are also using other sympathomimetic drugs (stimulants or appetite suppressants and drugs used to treat congestion and asthma).

Do not take too much caffeine (e.g. coffee, tea and some canned drinks) when you are taking Grippostad Day.

Do not take any other medicines containing paracetamol. Taking too much paracetamol can lead to serious liver damage which can sometimes be fatal. You should take particular care if you have liver or kidney disease. You are more at risk of overdose if you are an alcoholic.

You should see your doctor if:

- you develop a high fever
- you develop signs of other infection such as feeling unwell, night sweats, tiredness, pain, or swelling
- your symptoms do not get better after three days.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

The following medicines may affect or be affected by Grippostad Day.

You should not take Grippostad Day with any of the following medicines without first talking to your doctor:

- **Monoamine oxidase inhibitors (MAOIs)**, including moclobemide
- Sympathomimetic drugs (stimulants or appetite suppressants and drugs used to treat congestion and asthma)
- Beta blockers and other antihypertensive drugs (used to treat high blood pressure), including debrisoquine, guanethidine, reserpine, and methyldopa
- Tricyclic antidepressants, for example amitriptyline, used to treat feeling sad (depression)
- Cardiac glycosides (drugs used to control heart rhythms or contractions) for example digoxin
- Ergot alkaloids (drugs used to treat migraine), for example ergotamine and methysergide
- Anticoagulants (drugs used to thin the blood, such as warfarin)

- Propantheline (used to treat gastrointestinal disorders, wetting (enuresis), and excessive sweating (hyperhidrosis))
- Pethidine and pentazocine (pain killers)
- Metoclopramide or domperidone (used to treat nausea and vomiting)
- Colestyramine (used to lower blood cholesterol)
- Carbamazepine, phenobarbital, phenytoin, and primidone (used to treat epilepsy)
- Rifampicin (an antibiotic)
- St John's Wort (used to treat depression).

Do not take Grippostad Day with other products containing paracetamol.

Taking Grippostad Day with food and drink

Do not drink alcohol (wine, beer, spirits) whilst taking this medicine.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Do not take this product if you are pregnant or while breast-feeding.

Driving and using machines

Take care when driving. Grippostad Day may affect your reactions, especially:

- at the start of treatment
- after increasing your dose
- when changing from a different medication
- if you also drink alcohol.

Do not operate any tools or machines or drive if your reactions are affected.

Important information about some of the ingredients of Grippostad Day

- **Warning:**

Grippostad Day contains paracetamol and a drug to reduce congestion in the nasal passages (decongestant). Do not take with any other product for the relief of flu, colds or nasal congestion, or with other products containing paracetamol.

3. How to take Grippostad Day

Always take Grippostad Day exactly as described in this leaflet.

You should check with your doctor or pharmacist if you are not sure.

The usual dose is:

Adults (including the elderly) and children aged over 16 years:

Take two capsules every four to six hours a day if necessary.

Do not take more than 12 capsules a day (in any 24-hour period).

Children aged 12 to 16 years

Take two capsules every four to six hours a day if necessary.

Do not take more than 10 capsules a day (in any 24-hour period)

Do not give more than four doses in any 24-hour period.

Leave at least 4 hours between doses.

Do not take a higher dose than the recommended dose without first talking to your doctor.

Grippostad Day should be used during daytime only, as it contains caffeine, which may cause sleeplessness.

How to take Grippostad Day

The capsules should be taken by mouth.

Swallow the capsules whole with water. Do not chew.

For how long should you take Grippostad Day

If your symptoms do not get better after three days, talk to your doctor.

Children under 12 years

Do not give Grippostad Day to children under 12 years old.

If you take more Grippostad Day than you should

Contact your doctor or nearest emergency department immediately for advice if:

- You accidentally take too many capsules

- A child takes any Grippostad Day.

You should do this straight away even if you feel well. If you delay there is a risk of serious liver damage. Take your medicine and this leaflet with you so that the medical staff know what you have taken.

You are at greater risk of overdose if:

- you are taking any of the following medicines for more than a few weeks:
 - carbamazepine, phenobarbital, phenytoin, and primidone (used to treat epilepsy)
 - rifampicin (an antibiotic)
 - St John's Wort (used to treat depression)
- you regularly drink too much alcohol
- you have a shortage of a protein called glutathione. This can be due to:
 - an eating disorder such as lack or loss of appetite
 - starvation, or if you lose weight even when eating normally (a body wasting disease called cachexia)
 - cystic fibrosis (a hereditary disease causing breathing difficulties)
 - HIV infection (AIDS).

Symptoms of overdose in the first 24 hours are:

- Pale skin (pallor)
- Feeling sick (nausea)
- Being sick (vomiting)
- Lack of appetite (anorexia)
- Tummy pain (abdominal pain).

Other symptoms are:

- Problems with breaking down glucose
- Too much acid in the body (metabolic acidosis).

Severe overdose can be fatal and lead to:

- Liver failure
- Brain damage (encephalopathy)
- Bleeding (haemorrhage)
- Low blood sugar levels (hypoglycaemia)
- Swelling of the brain (cerebral oedema)
- Kidney failure with loin pain (acute tubular necrosis)
- Blood in the urine (haematuria)
- Protein in the urine (proteinuria)
- Irregular heartbeat (cardiac arrhythmia)
- Inflamed pancreas (pancreatitis)
- Pain in the upper part of the tummy (epigastric pain)
- Being sick (vomiting)
- Increased urine production (diuresis)

- Rapid heartbeat (tachycardia)
- Stimulation of the nervous system including:
 - difficulty sleeping (insomnia)
 - restlessness
 - excitement
 - feeling anxious (agitation)
 - feeling nervous and flustered (jitteriness)
 - uncontrolled shaking (tremors)
 - fits (convulsions).
- Other effects similar to those under section 4 “Possible Side Effects” in this leaflet
- High blood pressure (hypertension)
- Slow heartbeat (reflex bradycardia)
- Confusion
- Seeing or hearing things that are not there (hallucinations).

If you forget to take Grippostad Day

Do not take a double dose to make up for a forgotten capsule.

Make sure your next dose is taken at least four hours after your previous dose.

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

4. Possible side effects

Like all medicines, Grippostad Day can cause side effects, although not everybody gets them.

The evaluation of the side effects is based on the following frequencies:

| | |
|--------------------|---|
| Very common | Affects more than 1 user in 10 |
| Common | Affects 1 to 10 users in 100 |
| Uncommon | Affects 1 to 10 users in 1,000 |
| Rare | Affects 1 to 10 users in 10,000 |
| Very rare | Affects less than 1 user in 10,000 |
| Not known | frequency cannot be estimated from the available data |

If you experience any of the following stop using the medicine and seek immediate help

- Allergic reactions:
 - swelling of the skin, of the face and lips, tongue and throat, or voice box (angioedema)
 - difficulty breathing (dyspnea)
 - sweating

- feeling sick (nausea)
- low blood pressure (hypotension) leading to shock
- severe allergic reaction (anaphylaxis)

If you experience any of the following, stop using the medicine and talk to your doctor

- Allergic skin reactions (cutaneous hypersensitivity reactions) including:
 - skin rashes
 - Stevens Johnson syndrome (a serious illness with blistering of the skin, mouth, eyes and genitals)
 - Toxic Epidermal Necrolysis (severe blistering and peeling of the skin)
- Allergic reactions, for example: rash, hives (urticaria), skin inflammation (allergic dermatitis)
- Allergic (hypersensitivity) reactions. If you have had an allergic reaction with other sympathomimetic drugs (such as pseudoephedrine) before, you are more likely to have an allergic reaction (cross-sensitivity)

Very rare:

- Liver problems (hepatic dysfunction)

Not known:

- Low numbers of blood cells called platelets or thrombocytes (thrombocytopenia)
- Low numbers of white blood cells called leukocytes (leukopenia)
- A severe lack of white blood cells (agranulocytosis)
- Low numbers of red and white blood cells (pancytopenia)
- Tiredness
- Headache
- Dizziness
- Difficulty sleeping (insomnia)
- Anxiety
- Nervousness
- Feeling irritated (irritability)
- Restlessness
- Feeling excited (excitability)
- Worsening of raised pressure in the eye (pre-existing narrow-angle glaucoma) (see also section 2. “DO NOT take Grippostad Day”)
- Dilated pupils (mydriasis)
- Sudden raised pressure in the eye (acute angle closure glaucoma)
- High blood pressure (hypertension)
- Feeling your heartbeat (palpitations)
- Rapid heartbeat (tachycardia)

- Narrowing of the upper airways (bronchospasm)
- Dry mouth
- Feeling sick (nausea)
- Being sick (vomiting)
- Runny stools (diarrhoea)
- Lack of appetite (anorexia)
- Kidney problems (renal dysfunction)
- Difficulty urinating (dysuria) or inability to urinate (urinary retention). This is more likely to occur if your bladder is blocked, for example if you have an enlarged prostate. See also section 2. "Take special care."

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Grippostad Day

Keep out of the reach and sight of children.

Do not use Grippostad Day after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Grippostad Day contains

The active substances are:

- paracetamol
- caffeine
- phenylephrine hydrochloride

Each capsule contains:

- 300 mg paracetamol
- 25 mg caffeine
- 5 mg phenylephrine hydrochloride.

The other ingredients are:

- ascorbic acid

- glycerol tristearate
- sodium laurylsulfate
- colloidal anhydrous silica
- magnesium stearate

The other ingredients in the capsule shell are:

- gelatin
- titanium dioxide (E 171)
- yellow iron oxide (E 172).

What Grippostad Day Capsules looks like and contents of the pack

Grippostad Day Capsules are hard capsules with a white body and yellow cap.

Grippostad Day Capsules are available in:

- Aluminium (Alu/Alu) blister strips, sealed with aluminium foil

Blister strips are packed into cardboard cartons.

Pack sizes are 10, 12, 20 and 24 capsules.

Not all pack sizes are marketed.

Marketing Authorisation Holder

STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel, Germany

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

Germany: Grippostad Tag Hartkapseln

United Kingdom: Grippostad Day Capsules

This leaflet was last revised in 02/2014.