

Package leaflet: Information for the user

Altermol 500 mg/30 mg, tablet

paracetamol /codeine

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Altermol is and what it is used for

Altermol contains two pain-relieving substances (paracetamol and codeine) that work in different ways. Paracetamol has both pain-relieving and fever-reducing effects. Codeine reinforces the pain-relieving effect.

This product contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It can be used on its own or in combination with other pain killers such as paracetamol.

Altermol can be used in adults and adolescents over 12 years of age for the short-term relief of moderate pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone.

2. What you need to know before you take Altermol

Do not take Altermol

- if you are allergic to paracetamol, codeine or any of the other ingredients of this medicine (listed in section 6)
- for pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome
- if you know that you metabolise very rapidly codeine into morphine
- if you are breastfeeding
- if you suffer from bile duct problems.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Altermol if:

- you have asthma. Take special care with Altermol if you have asthma and are hypersensitive to acetylsalicylic acid
- you have alcohol problems
- you have liver damage
- if you have a serious infection such as blood poisoning, as this may increase the risk of so-called metabolic acidosis. Signs of metabolic acidosis include: strained breathing (deep inhalation and rapid

exhalation), nausea and vomiting. Seek medical attention immediately if you get a combination of these symptoms.

- you are taking other medicines containing paracetamol.

During treatment with Altermol, 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).
- you experience pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine.
- you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

Do not take Altermol together with alcohol.

If you use other pain-relieving medicines containing paracetamol, you must not use Altermol unless you have first discussed it with your doctor or pharmacist.

Never take more Altermol tablets than your doctor has prescribed. **Higher doses than those recommended will not result in improved pain relief, but instead carry the risk of impaired respiratory function and very serious liver damage.** Symptoms of liver damage do not normally appear until after a few days have passed. It is therefore important that you seek medical advice as soon as possible if you have taken too large a dose.

Tolerance, dependence, and addiction

This medicine contains codeine which is an opioid medicine. It can cause dependence and/or addiction.

Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Altermol can also lead to dependence, abuse and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to Altermol if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking Altermol, it could be a sign that you have become dependent or addicted:

- You need to take the medicine for longer than advised by your doctor
- You need to take more than the recommended dose

- You might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain
- You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects')

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop taking Altermol).

Sleep-related breathing disorders

Altermol can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces pain relief. Some people have a variation of this enzyme and this can affect people in different ways. In some people, morphine is not produced or produced in very small quantities, and it will not provide enough pain relief. Other people are more likely to get serious side effects because a very high amount of morphine is produced. If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

Children and adolescents

Use in children and adolescents after surgery

Altermol should not be used for pain relief in children and adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome.

Use in children with breathing problems

Altermol is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

Other medicines and Altermol

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

Some medicines/natural remedies can affect or be affected by treatment with Altermol, for example

- Quinidine (medicine for irregular heart rhythm).
- Neuroleptics (medicine for psychological disorders).
- Antidepressants.
- Warfarin (blood-thinning medicine). Contact your doctor if you take more than 2 tablets of Altermol a day for 5 days in a row. There is a risk that this may have an impact on the efficacy of warfarin.
- Probenecid (medicine for gout).
- Some medicines for epilepsy (phenytoin, phenobarbital and carbamazepine).
- Rifampicin (medicine for tuberculosis).
- Cholestyramine (medicine for high blood lipids). Altermol and cholestyramine should be taken at least one hour apart.
- Chloramphenicol for injection (medicine for bacterial infections). However, chloramphenicol for eye infections can be used.
- St John's wort extract (included in some herbal medicinal products).
- Metoclopramide (medicine for nausea).
- Terbinafine (antifungal medicine).

- Barbiturates (medicine used in general anesthesia).
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called high anion gap metabolic acidosis) that must have urgent treatment (see section 2).
- Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain).

Concomitant use of Altermol and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However if your doctor does prescribe Altermol together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Altermol with food, drink and alcohol

The risk of liver damage from taking too much Altermol is increased by alcohol abuse.

Never take Altermol together with alcohol.

Altermol tablets can be taken with fluid on an empty stomach or with a meal.

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 before taking this medicine

Pregnancy

Do not take Altermol if you are pregnant or think you may be pregnant unless your doctor has advised you to do so.

Breast-feeding

Do not take codeine while you are breastfeeding. Codeine and morphine passes into breast milk.

Driving and using machines

Altermol can impair your ability to react and make you tired and drowsy, which you should bear in mind on occasions when full attention is required, for example driving a car or doing precision work.

Altermol contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Altermol

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Altermol, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also, If you stop taking Altermol).

NB! Doses higher than those recommended may involve serious risks.

The recommended dose is:

Adults

1-2 tablets 1-4 times in 24 hours. Wait at least 4 hours before taking another dose.
Do not take more than 8 tablets in 24 hours.

Altermol should be used for the shortest duration necessary to relieve symptoms. If no effective pain relief is achieved while taking the medicine, you should seek the advice of a physician.

Children aged 12 years and above:

40-50 kg: 1-2 tablets 1-4 times in 24 hours. Wait at least 6 hours before taking another dose.
Do not take more than 5 tablets in 24 hours.

34-40 kg: 1 tablet 1-4 times in 24 hours. Wait at least 6 hours before taking another dose.
Do not take more than 4 tablets in 24 hours.

As the Altermol tablet is not able to split in two equal doses, children weighing less than 34 kg cannot be treated without exceeding the maximum recommended paracetamol dose. Ask your doctor for advice.

Children aged less than 12 years:

Altermol should not be taken due to the risk of severe breathing problems.

If you take more Altermol than you should

Tell your doctor or pharmacist if you have taken more Altermol tablets than listed here or more than the doctor has prescribed and you therefore feel unwell. Bring the package with you.

In the event of overdose with Altermol, the main risks are the liver toxic effect of paracetamol and the respiratory depressant effect of codeine.
Higher dose of Altermol than the recommended is dangerous and may cause long-term damage.

You might not experience any symptoms (normally symptoms emerge after a few days). *Even if you feel well, there may be a risk of serious liver damage.*

It is important that you contact your doctor as soon as possible for advice. In case of suspected overdose, you should have immediate treatment.

Symptoms of overdose:

Nausea, vomiting and abdominal pain (after ingestion and for the first few days).

- Convulsions in children.
- Small (miotic) pupils, drowsiness, difficulty breathing with blue discoloration of the skin and mucous membranes. Reduced breathing can lead to unconsciousness (coma).

If you forget to take Altermol

If you forget a dose, take it as soon as you remember it. However, if it is time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose. Remember not to shorten your dosing interval. For adults there should be at least 4 hours between each dose intake and for adolescents over 12 years of age there should be at least 6 hours between each dose intake.

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

4. Possible side effects

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

You should **stop taking** Altermol and **see your doctor immediately** if you experience symptoms of angioedema, *which is a rare side effect (may affect up to 1 in 1,000 people).*

Symptoms include:

- swollen face, tongue or throat
- difficulty to swallow
- hives and difficulties to breathe.

Not known (*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:

Common (*may affect up to 1 in 10 people*): Tiredness, nausea, constipation.

Uncommon (*may affect up to 1 in 100 people*): Convulsions in the bile ducts can occur in people with this tendency.

Rare (*may affect up to 1 in 1,000 people*): Skin rash, liver damage, impaired kidney function, allergic reactions.

Very rare (*may affect up to 1 in 10,000 people*): Inflammation of the pancreas.

Not known (*cannot be estimated from the available data*): Dizziness, problem affecting a valve in the intestines (sphincter of Oddi dysfunction).

Very rare cases of serious skin reactions have been reported.

Liver damage can occur from use of paracetamol in connection with alcohol abuse. If you use Altermol for a prolonged period the risk of kidney damage cannot be ruled out.

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 [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 Altermol

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

Store this medicine in a safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been intended for them.

This medicine does not require any special storage conditions.

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 Altermol contains

- The active substances are:
paracetamol 500 mg and codeine phosphate hemihydrate 30 mg.
- The other ingredients are:

Pregelatinized maize starch, stearic acid, povidone, lactose monohydrate, cellulose, microcrystalline (E460), talc (E553b), magnesium stearate.

What Altermol looks like and contents of the pack

White to almost white, capsule shaped, flat beveled, uncoated tablet, 17.5 x 7 mm, embossed with “PC2” on one side and with score line on the other side.

Blister package of A1/ clear PVC: 10, 20, 50 and 100 tablets.

HDPE container (white polyethylene bottle): 100 and 250 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Alternova A/S, Energivej 15, 5260 Odense S, Denmark

Manufacturer

Santa S. A.

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or

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

Sweden: Altermol

Norway: Altermol

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<Detailed information on this medicine is available on the web site of {MA/Agency}>