

PACKAGE LEAFLET: INFORMATION FOR THE USER

Cinfatos complex oral suspension

Paracetamol/Dextromethorphan hydrobromide/Pseudoephedrine hydrochloride

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

Follow the directions on the medicine given in this leaflet exactly or as directed by your doctor, pharmacist or nurse.

- Keep this leaflet, as you may need to read it again.
- If you have any questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible effects not listed in this leaflet. See section 4.
- You should see a doctor if you are an adult and your condition gets worse or does not improve after 5 days

What is in this leaflet:

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

1. What cinfatos complex is and what it is used for

Cinfatos complex contains a mixture of paracetamol, dextromethorphan and pseudoephedrine.

Paracetamol belongs to the group of drugs called non-steroidal anti-inflammatory (NSAIDs), so it is effective in reducing pain and fever.

Dextromethorphan has antitussive action (inhibits the cough reflex). Pseudoephedrine is effective in reducing nasal congestion.

The mixture is indicated for the symptomatic relief of common cold and flu processes that occur with mild or moderate pain, fever, unproductive cough (irritating or nervous cough) and nasal congestion for adults and adolescents from 12 years of age.

You should consult your doctor if your condition worsens or does not improve after 5 days of treatment.

2. What you need to know before you use cinfatos complex

Do not take cinfatos complex if:

- You are allergic (hypersensitive) to paracetamol, dextromethorphan, pseudoephedrine, other nasal decongestants or any of the other ingredients of this medicine (listed in section 6).
- You have a serious lung illness, have an asthmatic cough or a cough with abundant phlegm.
- You have severe high blood pressure (hypertension) or serious heart or blood vessel disease.
- You have been diagnosed with hyperthyroidism.
- You have been treated during the previous 2 weeks or are currently being treated with:
 - any monoamine oxidase inhibitor (MAOI) used for the treatment of depression, as it may cause an increase in blood pressure.
 - any medicine for Parkinson's disease or other diseases as well as any other serotonin reuptake inhibitors used for the treatment of depression, such as fluoxetine or paroxetine
 - bupropion, which is a medicine used to stop smoking
 - linezolid, which is an antibacterial drug (see subsection, **cinfatos complex with other medicines**)
- You are pregnant and are in the first 3 months of pregnancy.

Warnings and Precautions

Do not take more medicine than recommended in section.

3. How to use cinfatos complex.

Concomitant use of this medication with other medicines containing paracetamol should be avoided as high doses may lead to liver damage. Do not use more than one drug containing paracetamol without talking to your doctor.

Consult your doctor or pharmacist before starting to take **cinfatos complex** if you are a patient with:

- Kidney, liver, heart or lung disease or anaemia.
- Epilepsy: You should consult your doctor before taking this medicine because it decreases the effectiveness and enhances the hepatotoxicity of one of the active ingredients when used at the same time.
- Asthma sensitive to acetylsalicylic acid.
- Diabetes.
- Cardiovascular disease, hypertension.
- High eye pressure (glaucoma).
- Difficulty urinating, urinary blockage.
- Persistent or chronic cough, such as smoker's cough. Chronic cough may be an early symptom of asthma, especially in children.
- Atopic dermatitis (inflammatory skin disease characterised by erythema, itching, exudation, crusting and scaling, which begins in childhood in individuals with hereditary allergic predisposition).
- Sedated, weakened or bedridden.
- Chronic alcoholics should be careful not to exceed the recommended amount of this drug in section
- If diarrhoea occurs during treatment, stop taking this medication immediately and consult your doctor.

There have been reports of abuse of medications containing dextromethorphan in adolescents, so this possibility should be taken into account because serious adverse effects can occur (see subsection, **If you take more cinfatos complex than you should**).

If you take other medicines containing nasal decongestants, you should not take this medicine.

You must stop treatment at least 24 hours before surgery.

Concurrent use of cocaine with pseudoephedrine may increase cardiovascular effects and the risk of adverse effects.

Children and adolescents

Do not administer to children less than 12 years of age.

Elderly patients

Elderly people are more sensitive to adverse effects, so dose adjustment may be necessary. Consult your doctor.

Other medicines and cinfatos complex

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

In particular, if you are using any of the following drugs or substances with the pharmacological effect listed below, you may need to modify the dose of some of them or stop treatment:

- Urinary alkalinisers (sodium bicarbonate or citrate), as they can cause pseudoephedrine to be eliminated more slowly and increase its effect and toxicity.
- Inhalation anaesthetics, as they may increase the risk of heart problems. Monoamine oxidase inhibitors (MAOIs) used to treat depression (moclobemide, tranylcypromine, fluoxetine, paroxetine, bupropion), Parkinson's disease (selegiline) or other diseases, such as cancer (procarbazine), infections (linezolid, furazolidine). If you are taking any of these, you should stop taking them for at least 15 days both before and after the administration of **cinfatos complex**. If not, it could lead to a serious increase in blood pressure, very high fever or headache because it contains pseudoephedrine.
- Medications to treat depression and seizures: barbiturates (used as hypnotics, sedatives and anticonvulsants)
- Medications to treat epilepsy: antiepileptics (lamotrigine, phenytoin or other hydantoin, phenobarbital, methylphenobarbital, primidone, carbamazepine)
- Levodopa (used to treat Parkinson's) as it may increase the heart's rhythm (arrhythmias).
- Nervous system stimulants (amphetamines, xanthines) as they can cause nervousness, irritability, insomnia or possibly convulsions or altered heart rhythm (arrhythmias), as they may increase the effects of pseudoephedrine, causing a serious increase in blood pressure, very high fever or headache.
- Cocaine, which stimulates the nervous system and may increase the adverse effects on the heart if used in combination with pseudoephedrine.
- Central nervous system depressants (some of those used to treat: mental illness, allergy or Parkinson's disease, for example)
- Some medications to lower blood pressure and treat heart rhythm disturbances or to suppress urine elimination, such as beta blockers (e.g. propranolol), ACE inhibitors, loop diuretics (e.g. furosemide group type), rauwolfia alkaloids (e.g. reserpine, amiodarone and quinidine), as they may decrease the efficacy of these drugs.

- Digitalis glycosides (used for the heart) as they can cause alterations in the heart rhythm.
- Nitrates (used for the treatment of angina), because the effects of the nitrates may be lessened.
- Medication to prevent blood clots: oral anticoagulants (acenocoumarol, warfarin).
- Medicines to lower blood cholesterol levels: cholestyramine.
- Thyroid hormones (used for thyroid diseases), as the effects of both hormones and pseudoephedrine can be increased.
- Medicines to treat tuberculosis: isoniazid, rifampicin.
- Medicines used to treat gout: probenecid and sulfinpyrazone.
- Medications used to prevent nausea and vomiting: metoclopramide and domperidone.
- Anti-inflammatories: celecoxib, parecoxib and valdecoxib.
- Expectorants and mucolytics (used to remove phlegm and mucus).

You should stop taking any of the following medications for at least 15 days both before and after the administration of **cinfastos complex**, as excitation, high blood pressure or fever over 40°C (hyperpyrexia) may occur:

- Monoamine oxidase inhibitor (MAOI) anti-depressants: moclobemide, tranylcypromine.
- Serotonin reuptake inhibitor anti-depressants: paroxetine, fluoxetine.
- Bupropion (used to stop smoking)
- Linezolid (used as an antibacterial)
- Procarbazine (used to treat cancer)
- Selegiline (used to treat Parkinson's Disease)

Interference with diagnostic tests

If you are going to have an analytical test (blood, urine, skin using allergens), tell your doctor you are taking this medicine, as it may alter the results of such tests.

Cinfatos complex with food, drink and alcohol

You should not drink alcohol during treatment with this medication because it can cause serious adverse reactions.

Do not take with grapefruit juice or bitter orange. No other food or drink affects the effectiveness of the medication.

Pregnancy and lactation

If you are pregnant, breast-feeding, think you may be pregnant or intend to become pregnant, consult your doctor or pharmacist before using this medication.

Cinfatos complex is contraindicated during the first 3 months of pregnancy due to the presence of pseudoephedrine.

Paracetamol and pseudoephedrine pass into breast milk, so breastfeeding women should consult their doctor or pharmacist before taking this medication.

Driving and using machines

On rare occasions, drowsiness or mild dizziness may occur during treatment so, if you notice these symptoms, you should not drive or operate dangerous machines.

Cinfatos complex contains aspartame (E951), maltitol (E965), glycerol (E422), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216) and sodium citrate.

This medication may be harmful to people with phenylketonuria because it contains aspartame (E951) which is a source of phenylalanine.

This medication contains maltitol (E965). If you have been told you have intolerance to certain sugars, check with your doctor before taking this medication.

This medication may cause headache, stomach discomfort or diarrhoea as it contains glycerol (E422).

This medicinal product contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) and may produce (possibly delayed) allergic reactions.

Athletes are informed that this drug contains a component that tests positive in a doping control.

Follow the directions for use of this medicine exactly as given by your doctor or pharmacist. If in doubt, consult your doctor or pharmacist again.

The normal dose is:

Adults and adolescents over 12 years: 10mL every 6-8 hours (3-4 times a day). Do not take more than 3g of paracetamol every 24 hours (see subsection, **Warnings and precautions**).

Patients with liver or kidney disease should consult their doctor before taking this medication. If your doctor prescribes this medication, you should wait at least 8 hours between each dose.

Over 60 years: The dosage must be established by the doctor, as a reduction in the usual dose may be necessary.

Children and adolescents: This medicine is only for use in adolescents from 12 years of age. Children under 12 should not take it.

How to drink: This medicine is taken by mouth.

Shake well before use. Pour the amount of medicine to be taken into the measuring cup supplied with the bottle. Wash the measuring cup after use.

If the medication is taken at night, it should be taken a few hours before bedtime to reduce the possibility of insomnia in patients with difficulty sleeping.

The administration of this medicine is subject to the presence of all the symptoms. As these disappear, you should stop taking this medication.

If it gets worse, or if symptoms persist for more than 5 days (3 days, if you have fever), or other symptoms appear, such as high fever, skin rash or persistent headache, you should consult your doctor.

If you take more Cinfatos complex than you should

If you have taken more Cinfatos complex than you should, you may experience symptoms such as dizziness, vomiting, loss of appetite, jaundice (yellowing of the skin) or abdominal pain. Seizures, respiratory disorders, hallucinations, increased blood pressure, irregular heartbeat, excitability, tremors, palpitations or difficulty urinating may occur.

In case of overdose or accidental ingestion, consult your doctor or pharmacist immediately or call the Toxicological Information Service (phone 91 562 04 20), indicating the medication and the amount ingested.

If you have taken an overdose, go to a medical centre quickly even if there are no symptoms, as often they do not manifest themselves within 3 days of taking the overdose, even in cases of severe intoxication.

Treatment of overdose is most effective if started within 4 hours of taking the medication.

Patients being treated with barbiturates or chronic alcoholics may be more susceptible to the toxicity of a paracetamol overdose.

There have been cases of abuse with medications containing dextromethorphan, particularly in adolescents, with serious adverse effects such as: anxiety, panic, memory loss, tachycardia (acceleration of the heartbeat), lethargy, hypertension or hypotension (high or low blood pressure), mydriasis (eye pupil dilation), agitation, vertigo, gastrointestinal discomfort, hallucinations, slurred speech, nystagmus (uncontrolled and involuntary eye movement), fever, tachypnea (rapid and shallow breathing), brain damage, ataxia (uncoordinated movement), convulsions, respiratory depression, loss of consciousness, arrhythmias (irregular heartbeat), and death.

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

4. Possible side effects

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

Rare side effects (may affect up to 1 in 1,000 people):

- Discomfort.
- Lowered blood pressure (hypotension).
- Increased blood transaminase levels.

Very rare side effects (may affect up to 1 in 10,000 people):

- Kidney diseases, cloudy urine.
- Rash with or without irritation, itching, inflammation of the skin (dermatitis), jaundice (yellowing of the skin), severe skin reactions.
- Blood disorders (agranulocytosis, leukopenia, neutropenia, haemolytic anaemia) and hypoglycaemia (low blood sugar).

Adverse effects of unknown frequency (cannot be estimated from the available data):

- Heart rate disturbances (tachycardia, bradycardia and arrhythmias), palpitations, shortness of breath (dyspnoea).
- Symptoms of excitation, sleep disturbances, restlessness, dizziness, vertigo, headache, seizures, hallucinations and mental confusion. In the event of seizures or hallucinations, stop taking this medicine immediately.
- Involuntary closure of the eyelids (blepharospasm), photophobia and lachrymation.

- Nausea, vomiting, gastrointestinal discomfort, inflammation of the bowel, frequently with diarrhoea (ulcerative colitis) and constipation.
- Urine retention in men, pain or difficulty urinating.
- Trembling, pallor, weakness and increased sweating.

Paracetamol can damage the liver when taken in high doses or in prolonged treatments.

Notification of adverse effects

If you experience any type of adverse effect, consult your doctor or pharmacist, even if it is a possible side effect not listed in this leaflet. You can also communicate them directly to the Spanish System of Pharmacovigilance of Medicines for Human Use: <https://www.notificaram.es>. By communicating adverse effects you can help provide more information about the safety of this medicine.

5. How to store cinfatos complex

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

Do not use this medicine after the expiry date (stated on the carton after CAD). The expiry date is the last day of the month indicated.

Do not store above 25°C.

Medicines should not be disposed of via wastewater or household waste. If in doubt, ask your pharmacist how to dispose of medicine packaging you do not need. This will help to protect the environment.

6. Contents of the pack and other information

Composition of cinfatos complex:

Each mL of oral suspension contains:

Paracetamol	50mg
Dextromethorphan hydrobromide	2mg
Pseudoephedrine, hydrochloride	6mg

Other components (excipients) are maltitol (E965), glycerol (E422), sodium citrate (E331), citric acid monohydrate (E330), hypromellose, xanthan gum, methyl parahydroxybenzoate (E218), aspartame (E951), ammonium glycyrrhizate, propyl parahydroxybenzoate (E216), orange flavouring, orange juice flavouring, masking aroma and purified water.

What cinfatos complex looks like and contents of the pack

Cinfatos complex is a homogeneous, ivory white oral suspension with an orange odour packed in 125mL amber glass bottles. Each pack is supplied with a dosing cup marked at 2.5, 5.0, 7.5, 10 and 15mL.

Marketing authorisation holder and manufacturer

LABORATORIOS CINFA, SA
C/Olaz-Chipi, 10,
Polígono Industrial Areta
31620, Huarte/Pamplona, Navarre
SPAIN

This leaflet was last reviewed in March 2017

Detailed and updated information on this medicine is available on the website of the Spanish Agency of Medicines and Sanitary Products (AEMPS), <http://www.aemps.gob.es/>.