

Name of the medicinal product

EXPHARFLU tablets

Paracetamol 500 mg/ Phenylephrine hydrochloride 5 mg/ Chlorphenamine maleate 2 mg

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- You must contact a doctor if your symptoms worsen or do not improve after 5 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 package leaflet:

1. WHAT EXPHARFLU IS AND WHAT IT IS USED FOR
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1. WHAT EXPHARFLU IS AND WHAT IT IS USED FOR

This medicine is a combination of paracetamol, phenylephrine hydrochloride and chlorphenamine maleate. It is used in adults from 15 years and from a bodyweight of 50 kg for symptomatic treatment of:

- influenza and feverish complaint (headaches, neuralgia, various pains, fever);
- nasal congestion or obstruction, cold, rhinorrhea, watery eyes, repeating sneezing;
- acute congestive nasopharyngitis complaint whether infectious or allergic: rhinitis, sinusitis, pharyngitis, tubar catarrh, nasopharyngitis infections.

In case of bacterial infection, a therapy by antibiotics should be recommended.

Pharmacological classification: ATC code: N02BE ANILIDES

EXPHARFLU ® associates a sympathicomimetic, phenylephrine hydrochloride, and an antihistamine, chlorphenamine maleate and an antipyretic analgesic, paracetamol.

2. BEFORE YOU TAKE EXPHARFLU

Do not take EXPHARFLU in the following cases:

- Hypersensitivity to any of the ingredients
- Children under 15 years of age and under 50 kg
- Severe hypertension or uncontrolled treated hypertension
- History of cerebrovascular accidents or risk factors for cerebrovascular accidents
- Severe heart disease, coronary artery disease
- Glaucoma (increased intraocular pressure) (chlorphenamine and phenylephrine)
- Urinary retention associated with urethro-prostatic disorders (chlorphenamine and phenylephrine)
- Within 2 weeks time, treatment with MAOIs, drugs used for the treatment of some depressions
- Use of vasoconstrictor drugs such as bromocriptin, pergolide, lisuride, cabergoline, ergotamine, dihydroergotamine or others drugs to decongest nose administered by oral or nasal route (phenylpropanolamine, phenylephrine, ephedrine,...).
- History of convulsions

This medicine **MUST GENERALLY NOT BE USED**, unless otherwise instructed by your doctor, during pregnancy and breastfeeding.

IN CASE OF DOUBT, IT IS ESSENTIAL TO ASK THE ADVICE OF YOUR DOCTOR OR PHARMACIST

Be careful with EXPHARFLU:

Do not exceed the stated dose, do not prolong treatment more than 5 days and respect the above contra-indications.

Ask your doctor:

- in case of hypertension, heart disease, hyperthyroidism, confusion or diabetes;
- in case of concomitant use with drugs to treat migraine, especially drugs containing ergot alkaloid derivatives.
- if a surgery is planned and in case of use of halogenated anaesthetic agent it is recommended to discontinue the treatment a couple of days prior to the procedure because of risk of hypertension.
- in case of kidney failure, liver failure (including Gilbert's syndrome) and chronic alcoholism, the dose of paracetamol should be adapted.

The treatment should be discontinued in case of hypertension, tachycardia, palpitations and heart rhythm disorders, nausea or any neurological sign such as occurrence of headache or increased headache.

In case of purulent nasal secretion, or if fever lasts for more than 3 days or if symptoms last more than 5 days, **CONSULT YOUR DOCTOR**.

Athletes should be aware that this drug contains an active component (phenylephrine) which may induce a positive reaction to anti-doping tests.

Taking other medicines

Paracetamol absorption can distort the phosphotungstic acid and blood sugar level dosage when using the glucose-oxidase-peroxidase method. The drug should be used with care if associated with colestyramine, barbiturates, primidone, isoniazid, rifampicin, alcohol, probenecid, zidovudine, vitamin K antagonist anticoagulants,

This drug contains the vasoconstrictor phenylephrine, and the antihistaminic chlorphenamine that should not be combined with alcohol or with other vasoconstrictor compounds such as bromocriptine, pergolide, lisuride, cabergolide, ergotamine, dihydroergotamine, methylergometrine, linezolid or with any other oral or nasal drug used to treat nasal congestion, or with any other antihistaminic.

This drug should not be taken with other drugs containing ephedrine, phenylpropanolamine, pseudoephedrine or methylphenidate.

If you are taking or have recently taken another drug, including a drug obtained without prescription, ask your doctor or pharmacist.

If you have any doubt, do not hesitate to seek advice from your doctor or pharmacist.

Pregnancy and Breastfeeding:

EXPHARFLU is not recommended to pregnant women and nursing mothers.

IN GENERAL, ALWAYS ASK YOUR DOCTOR OR PHARMACIST BEFORE TAKING A MEDICINE DURING PREGNANCY OR WHILE BREASTFEEDING.

Driving vehicles and use of machines

Because of antihistamine presence, use with caution when driving a car or operating machinery as drowsiness may be associated with the use of the drug.

3. HOW TO TAKE EXPHARFLU

EXPHARFLU should only be administered to adults (adolescent over 15 years and over 50 kg of bodyweight)

Adults: 1 tablet - 2 or 4 times a day with an interval of 4 hours between each intake.

Do not exceed recommended dosages and 5 days of treatment.

If you have taken more EXPHARFLU tablets than you should:

An overdose of paracetamol may harm your liver.

In the event of overdose or accidental intoxication, inform your doctor immediately.

4. POSSIBLE SIDE EFFECTS

Like all medicines, EXPHARFLU tablets may cause side effects, although not everybody gets them:

Phenylephrine hydrochloride:

Palpitation, hypertension, insomnia, nervousness, stimulation, anxiety, psychotic events, confusion, irritability, headache, anorexia, nausea or vomiting (phenylephrine)

Chlorphenamine maleate:

Dry mouth, vision disorders (accommodation), urinary disorders, somnolence, constipation, vertigo, wheezing, hypotension, excitability in elderly patients.

Paracetamol:

Rare: dizziness, uneasiness, overdose and intoxication, allergic reactions, abdominal pain, diarrhoea, nausea, vomiting, constipation, troubled liver function, liver failure, liver necrosis, icterus, pruritus, rash, sweating, angioedema, hives, headaches.

Very rare: cloudy urines, thrombocytopenia, leucopenia, pancytopenia, neutropenia, haemolytic anaemia, agranulocytosis, severe allergic reactions have been reported.

Isolated cases: nephropathy (interstitial, nephritis, tubular necrosis) following the use of high doses of paracetamol, hepatitis, anaemia, anaphylactic shocks.

Discontinue use if allergic reactions such as wheezing, rash or itching develop.

Rarely stroke (cerebrovascular accident) has been reported in patients treated with drugs containing phenylephrine especially when warning or contra-indications had not been followed.

If you notice any side effects not mentioned in this package leaflet, or if some side effects become serious, please tell your doctor or pharmacist.

5. HOW TO STORE EXPHARFLU

Keep out of the reach and sight of children.

Do not use EXPHARFLU tablets after the expiry date stated on the outer pack.

Store at a temperature not exceeding 30°C.

Medicines must not be disposed of down the drain or with the domestic waste. Ask your pharmacist what you should do with unused medicines. These measures are to protect the environment.

6. FURTHER INFORMATION

What does EXPHARFLU contain?

The active substances are paracetamol (500 mg), phenylephrine hydrochloride (5mg) and chlorphenamine maleate (2 mg)

The other ingredients are: sodium starch glycolate, maize starch, microcrystalline cellulose, sodium benzoate (E211), sodium lauryl sulphate, polyvinyl pyrrolidone, tartrazine (E102), magnesium stearate, talc.

What EXPHARFLU looks like and contents of the pack?

This medicine is presented in the form of round, yellow, scored tablets.

Paper pouch of 4 tablets in alu-alu strip.

EXPHARFLU ® is a registered trademark

of Exphar s.a. Zoning Industriel de Nivelles Sud, Zone II – Avenue Thomas Edison 105 – 1402 Thines (Belgium)

Manufacturer:

MILAN LABORATORIES (INDIA) PVT. LTD.

PLOT NO 63-67 & 87, JAWAHAR CO.OP. INDUSTRIAL ESTATE, LTD

KAMOTHE , PANVEL, DIST. THANE,

MAHARASHTRA – 410209

INDIA

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Marketed by EXPHARLAB Ltd, 21 Boyle Street, 2nd floor, Onikan, Lagos, Nigeria.

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