PACKAGE LEAFLET:
INFORMATION FOR THE USER
Altridexamol 1000 mg Effervescent Tablets
Paracetamol 1000 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, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

IN THIS LEAFLET:

1. WHAT ALTRIDEXAMOL 1000 mg EFFERVESCENT TABLETS ARE AND WHAT THEY ARE USED FOR

Altridexamol 1000 mg Effervescent Tablets contain Paracetamol, which relieves pain (analgesic) and reduces the body temperature in fever (antipyretic).The tablets are ecommended for use in the treatment of mild to moderate pain and/or fever.

2. BEFORE YOU TAKE ALTRIDEXAMOL 1000 mg EFFERVESCENT TABLETS

Do not take Altridexamol 1000 mg Effervescent Tablets:

If you are allergic (hypersensitive) to Paracetamol or any of the ingredients of Altridexamol 1000 mg Effervescent Tablets.

Take special care with Altridexamol 1000 mg Effervescent Tablets

Tell your doctor:
- If you are suffering from kidney problems.
- If you are suffering from liver problems, including liver problems due to excessive alcohol consumption.
- If you have Gilbert's syndrome (mild jaundice).
- If you have hemolytic anemia (abnormal breakdown of red blood cells).
- If you are an asthmatic and sensitive to aspirin.
- If you are suffering from dehydration or chronic malnutrition.
- If you are on paracetamol containing drugs.
- If you have fever after paracetamol therapy.
- If you suffer from glucose-6-phosphate dehydrogenase deficiency (enzyme deficiency).

Do not use paracetamol unless prescribed by your doctor if you have an addiction to alcohol or liver damage. If this concerns you do not use with alcohol.
If you are already taking other pain medication containingparacetamol do not use Altridexamol 1000 mg Effervescent Tablets without first speaking to your doctor or a pharmacist.

Never take more Altridexamol 1000 mg Effervescent Tablets than recommended. A higher dose does not increase pain relief; instead it can cause severe liver damage. The ymptoms of liver damage occur first after a few days. It is important therefore that you contact your doctor as soon as possible if you have taken more Altridexamol 1000 mg Effervescent Tablets than recommended in this leaflet.
Do not use Altridexamol 1000 mg Effervescent Tablets in children and adolescents below 16 years of age.

3. HOW TO TAKE ALTRIDEXAMOL 1000 mg EFFERVESCENT TABLETS¨

You should take Altridexamol 1000 mg Effervescent Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Altridexamol 1000 mg Effervescent Tablets are for oral administration. Place the tablet in a full glass of water. Allow it to completely dissolve. Then drink the solution straight away.

If you have doubts on the correct dose of Altridexamol 1000 mg Effervescent Tablets to use please consult your doctor.

This medicinal product is for use, only in adults and adolescents aged 16 years and above.

Adults and adolescents :
Take one tablet (1000 mg) every six hours, up to a maximum of 4 tablets (4000 mg) in 24 hours.

Maximum daily dose:
The maximum daily dose of Paracetamol must not exceed 4 tablets (4000 mg).

Maximum single dose is 1000 mg (1 effervescent tablet)
The minimum time interval between two doses should be 6 hours.

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

If the pain persists for more than 5 days or the fever lasts for more than 3 days, or gets worse or other symptoms appear, you should stop the treatment and consult a doctor.

Kidney problems:
In moderate kidney problems: The usual dose is 500 mg repeated every 6 hours.
In severe kidney problems: The usual dose is 500 mg repeated every 8 hours.
Liver problems:
In case of problems with your liver please consult your doctor. Your doctor may decide to reduce the dose.
In chronic alcoholics, a dose of 2000 mg per day should not be exceeded.
Do not divide the 1000 mg tablet into two equal halves for the lower doses. Paracetamol tablets of lower strengths are available in the market.

Do not exceed the stated dose. Do not give to adolescents of 16 years of age and younger. Cap contains desiccant. Do not eat.

If you take more Altridexamol 1000 mg Effervescent Tablets than you should:
Symptoms of paracetamol overdose in the first 24 hours may include paleness, nausea (feeling sick), vomiting, lack of desire to eat and stomach pain. If you or someone you know accidentally takes more than the stated dose (overdose) you should contact a doctor immediately even if you feel well, because there is risk of serious, delayed liver damage

If you forget to take Altridexamol 1000 mg Effervescent Tablets:
If you forget to take a dose, take it as soon as you remember, unless it is almost time for your next dose. The minimum time interval between two doses should be 6 hours. Never take a double dose to make up for the one you have missed.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS
Like all medicines Altridexamol 1000 mg Effervescent Tablets can cause side effects, although not everybody gets them. You should stop taking Altridexamol 1000 mg Effervescent Tablets and see your doctor immediately if you experience symptoms like swelling in theface, tongue or throat. difficulty swallowing, red and itchy swellings on the skin and difficulty in breathing

Rare (affects less than 1 in 1.000 patients):

Bleeding problems or clotting disorders (Platelet disorders), decreased formation of cells, severe decrease in white blood cells which may lead to severe infections (agranulocytosis), frequent infections due to poorly functioning white blood cells or decrease in white blood cells (leucopenia), reduction in blood platelets, which increases the risk of bleeding or bruising (thrombocytopenia) abnormal breakdown of red blood cells, which may cause weakness or pale skin (haemolytic anaemia), decrease in blood count (pancylopenia), reduced neutrophil count in blood (neutropenia).

- Allergies (excluding swelling on the face, mouth, hands).
- Depression, confusion, sensing unreal things.
- Tremor, headache.
- Abnormal vision.
- Abnormal accumulation of fluid under the skin (oedema).
- Stomach pain, diarrhoea, nausea (feeling sick), vomiting or bleeding (haemorMage).
- Abnormal liver function, liver failure, death of liver cells (hepatic necrosis), jaundice.
- Dizziness, feeling of general discomfort or uneasiness (malaise), fever, drowsiness, drug interaction.
- Overdose and poisoning.

Very rare (affects less than 1 in 10.000 patients):

- Damage caused to the liver (hepatotoxicity).
- Immediate severe allergic reaction (hypersensitivity reaction requiring discontinuation of treatment).
- Low levels of glucose in the blood (hypoglycemia).
- Cloudy urine and kidney disorders.
- Life-threatening skin disease causing rash, skin peeling and sores (epidermal necrolysis).
- Allergic reaction of the skin (erythema multiforme).
- Severe life-threatening skin disease causing rash, skin peeling, sores (Stevens-Johnson syndrome).
- Accumulation of fluid in the voice box (larynx).
- Severe allergic reaction (anaphylactic shock).
- Decrease in red blood cells (anemia).
- Severe kidney impairment (renal alteration).
- Kidney disorder (nephrite interstitial).
- Blood in urine (haematuria).
- Inability to urinate (anuresis).
- Stomach ulcers and bleeding (gastrointestinal effects).
- Uneasiness

If any of the side effects gets serious or if you notice any side effects of listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ALTRIDEXAMOL 1000 mg EFFERVESCENT TABLETS

Keep out of the reach and sight of children and adolescents.
Do not use Altridexamol 1000 mg Effervescent Tablets after expiry date which is stated on the label after EXP. The expiry date refers to last day of that month.
Store below 25°C. Store in the original package in order to protect from moisture and light.
Do not use the product if you notice visible signs of deterioration like brown or black spots, bulging of tablets or discoloration.
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 Altridexamol 1000 mg effervescent tablets contain
The active ingredient is paracetamol. Each tablet contains1000 mg.
The other ingredients are anhydrous citric acid (E330), sodium bicarbonate (E500), sucralose (E955), sucrose monopalmitate (E473), sodium benzoate (E211), grapefruit flavour and kollidon 30 (E1201).

What Altridexamol 1000 mg Effervescent Tablets look like and contents of the pack
Altridexamol 1000 mg Effervescent Tablets are white to almost white round, flat tablets. The tablets are supplied in boxes containing 1 or 2 or 4 or 5 or 10 or 12 or 20 or 25 nylon/aluminium/PVC/lacquer blisters (2 tablets per blister) and a patient leaflet.

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