REXOM_{TM} WINAMOL TABLET

Paracetamol (250mg, 500mg, 650mg)

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What REXOM_{TM} Winamol is used for

- For the relief of fever
- For the relief from mild to moderate pain including: headache, migraine, backache, musculoskeletal pain (pain in bones, muscles, tendons, ligaments or nerves), muscle pain and sudden pain due to irritated or damaged nerve, painful periods, pain of osteoarthritis, toothache, pain after dental procedures/tooth extraction, pain after vaccination and the discomfort from colds, influenza and sore throats.

How REXOM_{TM} Winamol works

Paracetamol is a centrally acting analgesic and antipyretic with minimal anti-inflammatory properties. It works by relieving pain and reducing high temperature and fever.

Before you use REXOM_{TM} Winamol

-When you must not use it

It should not be used in individuals:

- known to be hypersensitive to paracetamol or other components of the product.
- which have severe and active liver impairment.
- taken other paracetamol containing medicines at the same time.

-Before you start to use it

- Paracetamol should be given with care to individuals with impaired kidney or liver function.
- Allergy alert: Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters or rash.
- It should also be given with care to individuals with alcohol dependence.

Pregnancy and lactation

Talk to you doctor before taking this medicine if you are pregnant, might become pregnant or are breastfeeding.

-Taking other medicines

Inform your doctor or pharmacist before taking this medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and REXOM $_{TM}$ Winamol may interfere with each other. They may be affected by REXOM $_{TM}$ Winamol or may affect how well it works.

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding.

How to use REXOM_{TM} Winamol

-How much to use

Always use $REXOM_{TM}$ Winamol exactly as your doctor has prescribed. You should check with your doctor or pharmacist if in doubt.

The usual dose:

Rexom_{TM} Winamol 250mg Tablet

Infants up to 3months: 5-10mg per kg/dose, on doctor's advice.

3 months - 1year: 60-120mg/dose

1-5 years: 120-250mg/dose 6-12 years: 250-500mg/dose

Above 12 years & adult: 500 1000mg/dose

These doses may be repeated every 4-6 hours when necessary. Maximum of 4 doses in 24 hours.

Rexom_{TM} Winamol 500mg Tablet

Above 12 years and adult: 1-2 tablets every 4-6 hours as required.

Maximum of 4 doses in 24 hours.

Rexom_{TM} Winamol 650mg Tablet

Adult: 1 to 1.5 tablet, 3 - 4 times a day or as directed by physician. Do not exceed 6 tablets a day.

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use it

Continue taking REXOM_{TM} Winamol as your doctor recommended. If symptoms persist, consult your doctor.

-If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too much $REXOM_{TM}$ Winamol may cause:

- Vomiting
- Abdominal pain
- · Low blood pressure
- Sweating
- Fatal liver failure
- Chemical-driven liver damage
- Major manifestations of liver failure such as jaundice, hypoglycemia (low glucose level) and metabolic acidosis (body produces excessive quantities of acid)

While you are using REXOM $_{\text{TM}}$ Winamol

-Things you must do

- Inform your doctor or pharmacist is symptoms persist after taking this medication.
- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking REXOM_{TM} Winamol.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not take more than the recommended dose unless your pharmacist or doctor tells you.
- Do not take any new medicines without consulting your doctor.
- Do not give REXOM_{TM} Winamol to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

- It is unlikely to impair ones ability to drive or use machinery.
- Avoid alcoholic food/beverages.

Side effects

Like all medicines, REXOM_{TM} Winamol can cause side effects, although not everybody gets them.

If symptoms persist, do not take the medicine and refer to the doctor.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

- Blood disorder reactions
- Cutaneous hypersensitivity reactions including skin rashes, angioedema (swelling beneath the skin's surface), Stevens Johnson Syndrome or Toxin Epidermal Necrolysis

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)

Storage and disposal of REXOM $_{\mbox{\scriptsize TM}}$ Winamol

-Storage

Store below 30°C. Protect from light. Keep medicine out of reach of children.

-Disposal

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.

Product description

-What it looks like

Rexom_{TM} Winamol 250mg Tablet

Orange colour, round biconvex with top score tablet.

Rexom_{TM} Winamol 500mg Tablet

White colour, circular biconvex uncoated tablet embossed with WINAMOL.

Rexom_{TM} Winamol 650mg Tablet

Yellow tablet with round, top-scored, embossed bottom Winamol 650.

-Ingredients

-Active ingredient Paracetamol

-Inactive ingredients Corn starch.

Rexom_{TM} Winamol 250mg Tablet

Starch, Magnesium stearate

Rexom_{TM} Winamol 500mg Tablet
Sodium starch glycolate, Potassium sorbate, talc, Povidone, Pregelatinized starch, Stearic acid.

Rexom_{TM} Winamol 650mg Tablet

Riboflavine, National starch, Magnesium stearate.

-MAL number

Rexom_{TM} Winamol 250mg Tablet MAL1991 1356XZ

Rexom_{TM} Winamol 500mg Tablet MAL1991 1400XZ

Rexom_{TM} Winamol 650mg Tablet MAL19991910XZ

Manufactured by and Product Registration Holder

KCK Pharmaceutical Industries Sdn.

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