

ERYSON GRANULES

Erythromycin Ethylsuccinate (200mg, 400mg)

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What Eryson Granules is used for

This medicine is used to treat and prevent infections such as upper respiratory tract infections, skin and soft tissue infections listed below:

- Pharyngitis, sinusitis (upper respiratory infection)
- Enteritis, pneumonia, bronchitis, (lower respiratory infection)
- Prophylaxis of surgical infection (infection of heart), rheumatic fever
- Diphtheria (inflammation of mucous membrane)
- Otitis media (middle ear inflammation)
- Erythrasma, Listeriosis, Diphtheria, Primary syphilis (Bacterial infection)

How Eryson Granules works

Eryson Granules consists of active substance Erythromycin. Erythromycin is an antibiotic that belongs to the group of medicines called macrolides. These medicines work by killing or stopping the growth of bacteria, which causes infections.

Before you use Eryson Granules

- When you must not take it

Do not use Eryson Granules:

- If you are hypersensitive, or have had an allergic reaction to Erythromycin, other macrolides or any other ingredients in this medicine.
- If you have previously developed liver problem while receiving Erythromycin.
- If you have history of (irregular heart beat) after receiving Erythromycin.
- If you have hearing loss, kidney or liver problem.
- If you are elderly.

- Before you start to use it

Take special care with Eryson Granules

Speak to your doctor if you have:

- liver disease
- irregular heart rhythm (arrhythmia)

- Taking other medicines

Please inform your doctor if you are taking or have recently taken any other medicines, including those obtained without a prescription, particularly:

- warfarin (thins the blood)
- seizure or epilepsy medicines including carbamazepine, phenytoin, and valproic acid
- antibiotics including chloramphenicol, penicillins and lincomycin
- terfenadine (antihistamine to treat allergy)
- digoxin (for heart problems)
- ergotamine or dihydroergotamine (for migraine)
- theophylline (for asthma or chronic obstructive pulmonary disease)
- zopiclone (induces sleep)
- lovastatin (blood cholesterol lowering medicine)
- other drug interaction includes: alfentanil, astemizole, bromocriptine, cyclosporine, disopyramide,

methylprednisolone, midazolam, nicoumalone, quinidine, tacrolimus, xanthines, and triazolam.

Your doctor should monitor you appropriately and may adjust your dosage of erythromycin as necessary.

If you are asked to provide a urine test, tell your doctor that you are taking Erythromycin as it may interfere with some tests.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant or planning to become pregnant. Erythromycin has been reported to cross the placental barrier.

Erythromycin passes into breast milk. Ask your doctor or pharmacist for advice before taking any medicine.

How to use Eryson Granules

Always take Eryson Granules exactly as your doctor has told you. The pharmacist's label should tell you how much to take and how often.

- How much to use

For oral use only.

The usual adult dose is 250mg but this may vary from person to person.

Your doctor will tell you how much you will need to take. This depends on the infection being treated and how severe it is.

For children, their doctor will work out the dose according to their age, body weight and how severe the infection is.

Adult:

For
200mg/mL
400mg (10mL), 6 hourly or 800mg (20mL), 12 hourly

For 400mg/5mL
400mg (5mL), 6 hourly or
800mg (10mL), 12 hourly

Usual adult limit:
Antibacterial up to 4g
daily

Children:
For 200mg/5mL dan 400mg/5mL
30-50mg/kg daily in divided
doses; double in severe infections

Children 2 to 8 years:
For 200mg/5mL
1g (25mL) daily in divided doses
For 400mg/5mL
1g (12.5mL) daily in divided
doses

Infant and children below 2 years:
For 200mg/5mL
500mg (12.5mL) daily in divided
doses
For 400mg/5mL
500mg (6.25mL) daily in divided
doses

- When to use it

If administration on a twice
daily schedule is desirable in
adults or children, one half of
the total daily dose may be
given every 12 hours at meal
time. Take with a full glass of
water at mealtime.

- How long to use it

It is important that you
complete your full course of
antibiotics; do not stop taking
the Granules early if you feel
better.

- If you forget to use it

If you miss a dose, take the
Granules as soon as you
remember and carry on as
before. If it is almost time for
your next dose, skip the missed
dose and continue as usual (do
not take a double dose to make
up for the forgotten dose).

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

- If you use too much
(overdose)

If you or a child accidentally
takes too much medicine,

contact your doctor or nearest
hospital emergency department
immediately. Take this leaflet,
the box and any Granules
remaining with you, if
possible.

Symptoms of overdose include
nausea, vomiting and diarrhoea
and loss of hearing.

While you are using it

- Things you must do
Always follow your doctor's
instructions carefully.

Tell your doctor if, for any
reason, you have not taken
your medicine exactly as
directed.

If you are about to start on any
new medicine, remind your
doctor and pharmacist that you
are taking Eryson Granules.

If you are taking Erythromycin
for an infection and you
symptoms do not improve
within a few days, or if they
become worse, tell your doctor.

Tell your doctor if you become
pregnant while taking
Erythromycin.

If you get severe diarrhoea tell
your doctor or pharmacist
immediately.

- Things you must not do

Do not stop taking your
medicine or lower the dosage
without checking with your
doctor.

Do not give your medicine to
anyone else, even if they have
the same condition as you.

- Things to be careful of

Be careful driving or operating
machinery until you know how
Eryson Granules affects you.

Side effects

Like all medicines,
Erythromycin Granules can
cause side effects, although not
everyone gets them.

Eryson granules may cause

severe allergy and serious skin
reactions. Stop using Eryson
granules and seek medical
assistance immediately if you
experience any of the
following symptoms:

- Skin reddening
- Blisters
- Rash
- Fever
- Sore throat
- Eye irritation

The following side effects are
common:

- gastrointestinal effects such
as abdominal discomfort
and cramp, nausea,
vomiting and diarrhea.

The following have also been
reported:

- oral candidiasis (sore mouth
or tongue, white patches in
mouth and/or on tongue)
- vaginal candidiasis (vaginal
itching and discharge)
- secondary infection
- pseudomembranous colitis
(inflammation of colon due
to overgrowth of bacteria)

The following side effects are
uncommon:

- itchiness
- hives
- skin rash
- anaphylaxis (allergic
reaction)

Hypersensitivity reaction may
occur due to hepatotoxicity
(toxic to the liver) effect of the
medicine. Symptoms indicative
of cholestasis (decreased bile
flow due to liver impairment)
include:

- upper abdominal pain
- nausea
- vomiting
- diarrhea
- abnormal liver function
values
- raised bilirubin in blood or
jaundice (yellowing of skin
and eyes)
- skin rashes
- fever
- unusual tiredness or
weakness

The following side effects are

rare:

- hearing loss, sometimes with ringing or buzzing
- heart toxicity (irregular or slow heart rate, recurrent fainting, sudden death)
- severe decreased white blood cells in blood
- central neurotoxicity including psychotic reactions and nightmares)
- myasthenia-like syndrome (weakness of muscle)
- pancreatitis (inflammation of the pancreas)

If you notice that the child vomits and/or irritability with feeding occurs, contact doctor immediately as it may be due to the Infantile Hypertrophic Pyloric Stenosis (IHPS)

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Eryson Granules

- Storage

Keep container tightly closed (loose pack and granules only). Store tightly closed in a refrigerator after reconstitution. Store in a dry place below 30°C. Protect from light. Keep out of reach of children.

- Disposal

Do not use the Granules after the expiry date is stated on the package. Discard 7 days after the reconstitution. 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

Eryson Granules 200mg:

An almost white powder when reconstituted forms a pink, fruity flavoured, homogenous suspension. Each 5 mL contains Erythromycin Ethylsuccinate equivalent to Erythromycin 200 mg.

Eryson Granules 400mg:

An almost white powder when reconstituted forms a pink, fruity flavoured, homogenous suspension. Each 5 mL contains Erythromycin Ethylsuccinate equivalent to Erythromycin 400 mg.

- Ingredients

- Active ingredient:

- Erythromycin Ethylsuccinate 200mg
- Erythromycin Ethylsuccinate 400mg

- Inactive ingredients:

- Cherry Red
- Saccharin Sodium
- Aerosil 200
- Flavour Strawberry
- Dextrose
- Orange flavour powder
- Propylparaben
- Sodium Carboxy Methyl Cellulose
- Methylparaben
- Trisodium citrate

- MAL number

Eryson Granules 200mg/5ml:
MAL19860679AZ

Eryson Granules 400mg/5ml:
MAL19860681AZ

Manufacturer

Duopharma Manufacturing (Bangi) Sdn Bhd (53667-M) Lot 2&4, Jalan P/7, Section 13, Bangi Industrial Estate, 43650 Bandar Baru Bangi, Selangor Darul Ehsan.

Product Registration Holder
Duopharma Manufacturing
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