Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Ranmoxy oral suspension.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from

https://www.ebs.tga.gov.au/ and may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the possible risks of taking amoxycillin against the expected benefits.

If you have any concerns about your child taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What RANMOXY Oral Suspension is used for

RANMOXY oral suspension contains the active ingredient amoxicillin, an antibiotic that belongs to a group of medicines called penicillins. These antibiotics work by killing the bacteria that cause infections. These may be infections of the chest (pneumonia), tonsils (tonsillitis), sinuses (sinusitis), urinary and genital tract, skin and fleshy tissues.

RANMOXY is used to treat infections in different parts of the body caused by bacteria.

RANMOXY is also used to prevent infections before, during and after surgery.

RANMOXY will not work against infections caused by viruses such as colds or the flu.

Your doctor may have prescribed **RANMOXY** for another reason.

Ask your doctor if you have any questions about why RANMOXY has been prescribed for your child.

This medicine is available only with a doctor's prescription.

RANMOXY is not addictive.

Before your child takes RANMOXY

When your child must not take it

RANMOXY must not be taken if your child has an allergy to:

- amoxycillin
- other penicillins
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itchiness, shortness of breath, swelling of the face, lips or tongue.

RANMOXY must not be taken if your child has an allergy to cephalosporins.

There may be an increased risk of your child being allergic to amoxycillin if they are allergic to cephalosporins.

RANMOXY must not be taken if the packaging is torn or shows signs of tampering.

RANMOXY must not be taken if the expiry date (EXP) printed on the pack has passed.

If this medicine is taken after the expiry date has passed, it may not work as well.

If you are not sure whether your child should start taking RANMOXY, contact your doctor.

Before your child starts to take it

Tell your doctor if your child has ever had any allergies to any antibiotics, any other medicines or any other substances, such as foods, preservatives or dyes.

Tell your doctor if your child has or has ever had any other health problems/medical conditions, including:

- glandular fever (mononucleosis)
- blood disorders
- liver or kidney problems

Tell your doctor or pharmacist if your child's urine has to be tested for sugar levels while taking **RANMOXY**.

Amoxycillin will produce false positive results when some of these tests are used. Your doctor will help you to identify the correct test.

If you have not told your doctor about any of the above, tell them before your child takes RANMOXY.

Taking other medicines

 Tell your doctor if your child is taking any other medicines, including medicines that you buy without a prescription from the pharmacy, supermarket or health food shop.

Some medicines may interfere with **RANMOXY**. These include:

- medicines used to treat gout (e.g. probenecid or allopurinol)
- other antibiotics (e.g. tetracyclines)
- anticoagulants (used to prevent blood clots) such as warfarin

These medicines may be affected by **RANMOXY**, or may affect how well it works. Your child may need different amounts of the medicine, or may need to take different medicines. Your doctor or pharmacist will advise you.

Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while taking **RANMOXY**.

How to give RANMOXY to your child

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to give

The usual dose of **RANMOXY** suspension is one dose taken three times a day. The dose may vary according to your child's weight.

How to give it

Shake the suspension well before measuring out the dose in a suitable measure. Make sure that the whole dose is swallowed each time. Space the doses as evenly as possible throughout the day. For example, if your child is taking **RANMOXY** three times a day, give a dose about every eight hours.

RANMOXY can be given with or without food. The effects of RANMOXY are not changed by food

How long to give it

Continue giving **RANMOXY** to your child until the course is finished or for as long as your doctor recommends. Do not stop giving **RANMOXY** to your child just because he/she feels better.

If the full course prescribed by your doctor is not completed, all of the bacteria causing the infection may not be killed. These bacteria may continue to grow and multiply so that the infection may not clear completely or it may return

If you forget to give it

If it is almost time for your child's next dose, skip the missed dose and give the next dose when you are meant to. Otherwise, give it as soon as you remember, and then go back to giving the doses as you would normally.

Do not give a double dose to make up for the dose that was missed.

If you have trouble remembering to give the doses, ask your pharmacist for some hints.

If your child takes too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) or go to the Accident and Emergency department of your nearest hospital, if you think that your child or anyone else may have taken too much RANMOXY.

Do this even if there are no signs of discomfort or poisoning.

Keep these telephone numbers handy.

If your child takes too much **RANMOXY**, he/she may get diarrhoea and nausea. There are unlikely to be any serious problems from an overdose of **RANMOXY**.

While you are giving RANMOXY

Things you must do

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

Otherwise, your doctor may think that it was not working as it should and change your child's treatment unnecessarily.

If the symptoms of your child's infection do not improve within a few days, or if they become worse, tell your doctor.

If your child develops itching with swelling or skin rash, or difficulty breathing while taking RANMOXY, do not give any more RANMOXY and contact your doctor immediately.

If your child gets severe diarrhoea tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after **RANMOXY** has been stopped.

Diarrhoea may mean that your child has a serious condition affecting the bowel. They may need urgent medical care.

Do not give any anti-diarrhoea medicine.

If your child gets a sore white mouth or tongue while taking or soon after stopping **RANMOXY**, tell your doctor. Also tell your doctor if your daughter gets vaginal itching or discharge.

This may mean your child has a fungal infection called thrush. Sometimes the use of amoxycillin allows fungi to grow and the above symptoms to occur. Amoxycillin does not work against fungi.

If your child is about to start taking any new medicine, tell your doctor and pharmacist that he/she is taking **RANMOXY**.

Tell all doctors, dentists and pharmacists who are treating your child that he/she is taking **RANMOXY**.

Things you must not do

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

Do not give RANMOXY to treat any other complaints unless your doctor tells you to.

Side effects

Check with your doctor as soon as possible if your child has any problems while taking **RANMOXY**, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, **RANMOXY** can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice your child has any of the following and they are troublesome or ongoing:

- soreness of the tongue or mouth
- overgrowth of yeast infections (thrush)
- diarrhoea (several loose bowel movements per day), indigestion, feeling sick or being sick

These side effects are usually mild.

Tell your doctor immediately if you notice your child has any of the following:

- · itching, rash
- · unusual bleeding or bruising
- · yellowing of the skin or eyes
- dark urine or pale stools
- · difficulty or pain on passing urine
- severe diarrhoea

These are serious side effects. Your child may need urgent medical attention. Serious side effects are rare.

If any of the following occur, stop giving RANMOXY and tell your doctor immediately or go to the Accident and Emergency department of your nearest hospital:

 wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. These could be symptoms of an allergic reaction.

These are very serious side effects. Your child may need urgent medical attention or hospitalisation. Serious side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making your child feel unwell.

Ask your doctor or pharmacist if you do not understand anything in this list.

Do not be alarmed by this list of possible side effects. Your child may not experience any of them.

After giving RANMOXY

Storage

Keep the RANMOXY suspension in the bottle until it is time to give a dose.

If you take the suspension out of the bottle, it may not keep well.

Keep the bottle in the refrigerator (but do not freeze it).

Keep all medicines well out of reach of children.

Do not use any RANMOXY suspension left in the bottle after the expiry date printed on the label or pack (the expiry date will be 14 days after the powder is reconstituted to form a suspension by the pharmacist). Ask your pharmacist what to do with any doses that are left over.

Disposal

If your doctor tells you to stop giving **RANMOXY** to your child, or it has passed the expiry date, ask your pharmacist what to do with any suspension that is left over.

Product description

What RANMOXY Suspension looks like

RANMOXY forms 100 mL of an orange suspension when it is reconstituted by the pharmacist, and is available in the following strengths:

- RANMOXY 125 mg amoxycillin/5 mL
- RANMOXY 250 mg amoxycillin/5 mL

Ingredients

- Ranmoxy 125mg/5mL contains 125 mg amoxycillin as the active ingredient.
- Ranmoxy 250mg/5mL contains 250 mg amoxycillin as the active ingredient.

Inactive ingredients:

- sorbito
- sunset yellow FCF CI 15985
- tutti frutti flavour
- xanthan gum
- sodium citrate
- colloidal anhydrous silica
- saccharin sodium

Australian Registration Numbers

- RANMOXY125 mg/5 mL : AUST R 137884
- RANMOXY250 mg/5 mL: AUST R 137885

Sponsor

Ranbaxy Australia Pty Ltd

Suite 4.02, Level 4, Building D 12-24 Talavera Road North Ryde, NSW 2113 Australia

This leaflet was prepared in Feb 2013