Medicines for Children

Information for parents and carers

Ivabradine to improve heart function

This leaflet is for parents and carers about how to use this medicine in children. Our information sometimes differs from that provided by the manufacturers, because their information is usually aimed at adults. Please read this leaflet carefully. Keep it somewhere safe so that you can read it again.

Name of medicine

Ivabradine

Brand name: Procoralan

Why is it important for my child to take this medicine?

Ivabradine makes the heart beat slower and with more strength so that blood is moved around the body more effectively.

What is Ivabradine available as?

Tablets: 2.5 mg, 5 mg and 7.5 mg; these contain small amounts of lactose, maltodextrin and polydextrose.

When should I give Ivabradine?

- Ivabradine is usually given **twice each day**. Give one dose in the morning and one in the evening. Ideally these times are 10–12 hours apart. For example, this could be between 7 and 8 am and between 7 and 8 pm.
- Give the medicine at about the same time(s) each day so that this becomes part of your child's daily routine, which will help you to remember.

How much should I give?

- Your child's healthcare team may suggest that your child has a low dose to start with. They may then increase the dose as your child gets used to the medicine and depending on how they respond to it.
- Do not reduce or change the dose unless your child's healthcare team tells you to.

Your child's healthcare team will work out the amount of medicine (the dose) that is right for your child. The dose will be shown on the medicine label.

It is important that you follow your child's healthcare team's instructions about how much to give.

How should I give it?

Ivabradine works best when given with, or just after, a meal or milk feed. Do not give it on an empty stomach.

Tablets should be swallowed with a glass of water, juice or squash. Your child should not chew the tablet. You can crush the tablet and mix it with a small amount of soft food such as yogurt, jam or mashed potato. Make sure your child swallows it all straight away, without chewing. You can also crush the tablet and mix it with a small amount of water. Your child should drink all the mixture straight away.

- Occasionally, the only way to provide the correct dose of ivabradine is to give part of a tablet or to disperse a tablet in a small amount of water and give some of the liquid mixture. Your health professional will explain if you need to do this and how to do it. You should not give part tablets or dissolve tablets in water unless you have been told that you need to.

When should the medicine start to work?

The medicine will start to work straight away.

What if my child is sick (vomits)?

- If your child is sick less than 30 minutes after having a dose of ivabradine, give them the same dose again.
- If your child is sick more than 30 minutes after having a dose of ivabradine, you do not need to give them another dose. Wait until the next normal dose.
- If your child is sick again, seek advice from your child's healthcare team. They will decide what to do based on your child's condition and the medicine involved.

What if I forget to give it?

If you remember within 4 hours, give your child the missed dose. For example, if you usually give a dose at 7 am, you can give the missed dose at any time up to 11 am. If you remember after this time, do not give the missed dose. Wait until it is time to give the next normal dose.

What if I think I have given too much?

It may be harmful to give too much ivabradine.

- If your child has any of the following symptoms, take them to hospital straight away:
  - they feel faint or dizzy
  - they are cold and sweaty
  - they have a weak or rapid heart rate (they may feel as though their heart is racing or fluttering)
  - they begin to breathe quickly.
- If you think you may have given your child too much ivabradine but they don't have any of the symptoms listed above, contact your doctor or local NHS services. Have the medicine or packaging with you if you telephone for advice.

Are there any possible side-effects?

We use medicines to make our children better, but sometimes they cause effects that we don't want (side-effects).

Side-effects you need to know about

- Your child may see spots of light or coloured flashes, particularly when going into bright light. This effect should wear off within 2 months of treatment.
- Your child's eyesight may be blurred (fuzzy).

- Your child may feel dizzy or light-headed when they stand up, or may faint. Encourage them to stand up slowly, and to sit or lie down if they feel dizzy or light-headed. If this happens often, contact your child's healthcare team to check your child's blood pressure, as it may be too low.
- Your child may feel that their heart is beating particularly quickly or slowly at times.
- Your child may get headaches.
- They may get muscle cramps.
- Your child may get stomach ache and feel sick (nausea) or be sick (vomit).
- They may also get constipated (have difficulty doing a poo). Encourage them to drink plenty of fluid and to eat foods that contain fibre (e.g. wholemeal foods, fruit and vegetables). If this is still a problem after 2 weeks, contact your child's healthcare team.
- Your child may get diarrhoea. Encourage them to drink plenty of water to replace the fluid they have lost. If it is severe, watery or has blood in it, or it goes on for more than 4 days, contact your child's healthcare team.

There may sometimes be other side-effects that are not listed above. If you notice anything unusual and are concerned, contact your doctor.

You can report any suspected side-effects to the UK safety scheme: MHRA Yellow Card.

More information on side-effects can be found in the Medicines for Children leaflet.

Can other medicines be given at the same time as Ivabradine?

- You can give your child medicines that contain paracetamol or ibuprofen, unless your child's healthcare team have told you not to.
- Ivabradine should not be taken with some medicines that you get on prescription. Tell your child's healthcare team about any other medicines your child is taking before giving ivabradine.
- Check with your child's healthcare team before giving any other medicines to your child. This includes herbal and complementary medicines.

Is there anything else I need to know about this medicine?

- Your child should not have grapefruit or grapefruit juice, as this can increase the amount of ivabradine in their blood, making side effects more likely.
- Ivabradine is also used to treat other heart conditions in children (e.g. postural tachycardia syndrome [POTS] and junctional ectopic tachycardia [JET]). If you look for information, make sure it is for the right condition.

General advice about medicines

- Try to give medicines at about the same times each day, to help you remember.
- If you are not sure a medicine is working, contact your child's healthcare team but continue to give the medicine as usual in the meantime. Do not give extra doses, as you may do harm.
- Only give this medicine to your child. Never give it to anyone else, even if their condition appears to be the same, as this could do harm.
- If you think someone else may have taken the medicine by accident, contact a doctor straight away.
- Make sure that you always have enough medicine. Order a new prescription at least 2 weeks before you will run out.
- Make sure that the medicine you have at home has not reached the 'use by' date on the packaging. Give old medicines to your pharmacist to dispose of.

Where should I keep this medicine?

- Keep the medicine in a cupboard, away from heat and direct sunlight. It does not need to be kept in the fridge.
- Make sure that children cannot see or reach the medicine.
- Keep the medicine in the container it came in.

Who to contact for more information

Your child's healthcare team will be able to give you more information about ivabradine and about other medicines used to improve heart function. You can also get useful information from:

England: NHS 111
Tel 111 nhs.uk

Scotland: NHS 24
Tel 111 nhs24.scot

Wales: NHS 111 Wales
Tel 111 111.wales.nhs.uk

Northern Ireland: NI Direct
nidirect.gov.uk

Children's Heart Federation
chfed.org.uk
Tel 0300 561 0065

RCPCH Royal College of Paediatrics and Child Health Leading the way in Children's Health
WellChild the national charity for sick children
NPPG Neonatal & Paediatric Pharmacy Group
Health & care information you can trust The Information Standard Certified Member

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The primary information source for this leaflet is the British National Formulary for Children. Details on other sources used can be found on www.medicinesforchildren.org.uk.
We take great care to make sure that the information in this leaflet is correct and up to date. However, medicines can be used in different ways for different patients. It is important that you ask the advice of your doctor or pharmacist if you are not sure about something. This leaflet is about the use of these medicines in the UK, and may not apply to other countries. The Royal College of Paediatrics and Child Health, Neonatal and Paediatric Pharmacists Group, WellChild and the contributors and editors cannot be held responsible for the accuracy of information, omissions of information, or any actions that may be taken as a consequence of reading this leaflet.