

# Combined Measles, Mumps and Rubella Vaccine

Read all of this leaflet carefully before your child is given this vaccine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This vaccine has been prescribed for you or your child. Do not pass it on to others. It may harm them.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or nurse.

## In this leaflet:

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### 1 What Priorix is and what it is used for

Priorix is a combined Measles, Mumps and Rubella (MMR) vaccine. It is used to boost the body's immune system to stop infection from measles, mumps and rubella.

This vaccine can be given to both adults and children. In this leaflet any reference to 'you' can also mean 'your child'.

#### How Priorix works

Priorix contains very small amounts of the measles, mumps and rubella viruses that have been weakened.

- There is not enough of these viruses in the vaccine to make you ill.
- There is just enough to trigger the body's immune system to prepare itself to protect against these viruses in the future.
- If you come into contact with measles, mumps or rubella in the future, you will not become ill because your body will fight off the infection.
- Viruses in the vaccine cannot be passed on to anyone else once you have had your injection.
- It is possible that Priorix will not work if you have already caught measles, mumps or rubella before you receive the MMR injection, but you have not yet shown any signs of being unwell.

### 2 Before having Priorix

#### Do not have Priorix if:

- you are allergic (hypersensitive) to any of the ingredients of Priorix (listed in Section 6)
- you are allergic (hypersensitive) to neomycin, an antibiotic used to treat skin infections
- you have any problem with the way your body fights disease (immunosuppression)
- you have a high temperature (fever).

Do not have Priorix if any of the above apply to you. If you are not sure, talk to your doctor, nurse or pharmacist before having Priorix.

#### Take special care with Priorix

Check with your doctor, nurse or pharmacist before having your vaccine if:

- you have an allergy to eggs
- you or a member of your family have a history of fits (convulsions)
- you or a member of your family have ever had an allergy problem, such as hayfever
- you have had measles or have been in contact with someone who has measles
- you have previously had a single or combined measles, mumps and rubella (MMR) vaccine and noticed that you bruised easily or bled for longer than usual. This could have been up to 6 weeks after the vaccine was given.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before having Priorix.

## Using other medicines and vaccines

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Priorix can affect the way some other medicines work. Also some other medicines can affect the way Priorix works.

Priorix can be given at the same time as most other routine childhood vaccines. The doctor will ensure that the vaccines are injected separately and into different parts of the body. Priorix should not be mixed with other vaccines in the same syringe.

In particular talk to your doctor if:

- you are taking a medicine that can affect the way that your body fights disease. You should not have Priorix if you are taking this type of medicine.
- you have recently received Priorix and you are due to have a test to see if you need a vaccination for tuberculosis (TB). This is because Priorix can affect the result of this test. You need to wait 4 to 6 weeks after receiving Priorix before the tuberculosis test can be given, for the doctor to see an accurate result.
- you have had a blood transfusion or received blood proteins. It is not recommended to receive Priorix for 3 months after this treatment.

## Pregnancy and breast-feeding

- Do not have Priorix if you are pregnant.
- Pregnancy should be avoided for one month after having this vaccine.
- Talk to your doctor or nurse if you are breast-feeding. It is sometimes possible to have the vaccine when you are breast-feeding.

## Driving and using machines

Priorix is not likely to affect you being able to drive or use any tools or machines.

### 3 How Priorix is given

#### How your vaccine is given

You will never be expected to give yourself this vaccine. It will always be given to you by a person qualified to do so.

You will have Priorix:

- as an injection under your skin, usually in the upper arm
- sometimes it is injected into muscle
- your doctor or nurse will usually wipe the skin clean around the place where you will have the injection using alcohol or another antiseptic.

#### How much is given

- Each time you receive Priorix, it will be given to you as a single 0.5 ml injection.
- The first dose is usually given at 12 to 15 months of age but Priorix can be used in children from 9 months of age, in adolescents and in adults.
- A second dose, sometimes called a 'booster' is given before your child starts school.
- Sometimes this second dose is given to young adults (adolescents) or adults if they have not already received it.
- It does not matter if the first dose is with Priorix or with another measles, mumps and rubella (MMR) vaccine. Priorix can still be given as a 'booster'.

#### Children under 12 months old

- Sometimes Priorix is given to children who are less than 12 months old if they are thought to be at high risk of infection.
- If this happens, another dose is usually given when the child is 12 to 15 months old. Your doctor will talk to you about this.

#### If you have more Priorix than you need

It is unlikely that you will be given too much Priorix.

## 4 Possible side effects

Like all vaccines, Priorix can cause side effects, although not everybody gets them. The following side effects may happen with this vaccine:

### Severe allergic reaction (affects less than 1 in 10,000 people)

If you have an allergic reaction, see your doctor straight away. The signs may include:

- sudden wheeziness and chest pain or chest tightness
- swelling of your eyelids, face, lips, mouth or tongue
- a lumpy skin rash or 'hives' anywhere on your body.

Other side effects include:

### Very common (affects more than 1 in 10 people)

- pain, redness at the injection site, fever

### Common (affects less than 1 in 10 people)

- swelling at the injection site
- a high fever
- rash
- runny nose or sneezing

### Uncommon (affects less than 1 in 100 people)

- diarrhoea or vomiting (being sick)
- feeling nervous
- pain in your ears or dizziness
- sore throat
- difficulty breathing
- coughing, possibly with some phlegm
- swollen lumps in your face, neck, underarms, chest, stomach (abdomen), groin or legs.
- loss of appetite
- sore eyes
- unusual crying
- unable to sleep

### Rare (affects less than 1 in 1000 people)

- fits (convulsions)

### Very Rare (affects less than 1 in 10,000 people)

- loss of sensation or feeling anywhere in the body, sometimes with 'pins and needles'
- stiff neck, sensitivity to light and severe headache (meningitis)
- itchiness
- red or purple spots on the skin
- blistering of the skin
- bruising easily and bleeding for a longer time than usual when you cut yourself.

Other side effects can happen two to four weeks after having the vaccine. These include:

- swollen lumps in the neck, underarms, chest, stomach (abdomen), groin or legs
- rash
- pain in your muscles
- pain in your joints. Older people are more likely to have joint pains than young children.

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.

## 5 How to store Priorix

- Keep out of the reach and sight of children.
- Store between 2°C and 8°C in a refrigerator.
- Do not freeze.
- Protect from light.
- Do not store for more than 3 hours after the injection has been made up.
- Do not use Priorix after the expiry date which is stated on the label and the carton.
- Store in the original package with this leaflet.
- Medicines should not be disposed of via wastewater or household waste. Your doctor or nurse will dispose of vaccine no longer required.

## 6 Further information

### What Priorix contains:

After mixing with water, each 0.5 ml dose contains not less than the following amounts of each virus type:  $10^3$  CCID<sub>50</sub> measles virus (Schwarz strain),  $10^{3.7}$  CCID<sub>50</sub> mumps virus (RIT 4385 strain),  $10^3$  CCID<sub>50</sub> rubella virus (RA 27/3 strain).

The term CCID<sub>50</sub> is a way of describing the number of live viruses present in the vaccine.

The other ingredients are lactose, mannitol, sorbitol and the following amino acids:

L-alanine, L-arginine, glycine, L-histidine, L-isoleucine, L-leucine, L-lysine HCl, L-methionine, L-phenylalanine, L-proline, L-serine, L-threonine, L-tryptophan, L-tyrosine, L-valine, L-aspartic acid, L-cysteine, L-cystine, L-hydroxyproline.

May contain traces of neomycin.

### What Priorix looks like and contents of the pack

Priorix is supplied as a whitish to slightly pink pellet in a single dose glass vial. In the same carton is a separate prefilled syringe, containing 0.5 ml of clear colourless sterile liquid (Water for Injections). This is used to mix with the pellet to make the vaccine that you will be injected with. When the vaccine is made up it will be clear peach to fuschia pink in colour.

### Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder:

SmithKline Beecham plc:

trading as GlaxoSmithKline UK  
Stockley Park West, Uxbridge  
Middlesex UB11 1BT

Manufacturer:

GlaxoSmithKline Biologicals s.a., Rixensart, Belgium

### Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

**Product name**      **Priorix**

Reference number    10592/0110

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