

Specific Patient Information

This information sheet has been developed in accordance with the current Arava[®] (leflunomide) Package leaflet and should be read in addition to this Package leaflet inserted in the medication packaging.

What should you know if you are a woman of childbearing potential, a woman with a wish to become pregnant or a man wishing to be a father?

If you are a woman of childbearing potential or a woman with a wish to become pregnant

- **Arava[®] may increase the risk of serious birth defects**

You may be at increased risk of having a baby with a birth defect if:

- You are pregnant when you start taking Arava[®], or
- You become pregnant while you are taking Arava[®], or
- You do not wait to become pregnant until you have stopped taking Arava[®] and followed the drug wash-out procedure described below, or
- You become pregnant within 2-years after you stopped Arava[®]

- **Precautions of use for Arava[®]**

If you are a woman of childbearing potential, you and your partner should take every precaution to avoid becoming pregnant, such as both partners using reliable birth control as recommended by your doctor when:

- You are currently taking Arava[®], or
- You have discontinued Arava[®] and are going through the drug wash-out procedure, or
- You have discontinued Arava[®] less than 2-years ago

It is VERY IMPORTANT that you contact your doctor IMMEDIATELY if your menstrual period is at all late or if for any other reason you believe you may be pregnant.

- **Arava[®] wash-out procedure**

After discontinuing Arava[®], your doctor will order you a drug wash-out procedure.

The aim of this procedure is to remove the drug rapidly and sufficiently from your body. The wash-out procedure consists of a full 11-day course of certain drugs which speed up the removal of Arava[®] from your body. This course is followed by 2 separate laboratory blood tests at least 14 days apart to assure a very low drug level in your body. If your Arava[®] levels are still too high, a repeated drug wash-out procedure may be necessary.

When it is confirmed that Arava[®] has been sufficiently removed from your body by the 2 separate laboratory blood tests, you should then wait for at least another six weeks before trying to become pregnant.

If you do not follow the drug wash-out procedure, it could take up to 2 years to reach this very low drug level in your blood.

If you are a man wishing to be a father

As it can not be excluded that Arava[®] passes into semen, reliable contraception during treatment with Arava[®] should be guaranteed.

When you want to father a child, you should discuss with your doctor who could advise you stop Arava[®] and then undergo the drug wash-out procedure (as described above).

When it is confirmed that Arava[®] has been sufficiently removed from your body, men should then wait for at least 3 months before fertilisation.

For further information, please contact your doctor.

An ad hoc advisory service is available for providing information on leflunomide plasma level testing for patients treated with Arava®. Your doctor will be able to provide you with further details on request.

SAGB.LEF.16.03.0238 March 2016