

Information for Patients about VERSAL (bilibizumab)

Read this information carefully before you, or your family member, start taking VERSAL and each time your prescription is refilled. This leaflet does not take the place of talking with your healthcare provider (HCP) about VERSAL. If you have questions about VERSAL talk to your HCP. Always follow your HCP's instructions for taking VERSAL.

What is the most important information I should know about VERSAL?

VERSAL is a medicine that affects your immune system and may lower the ability of your immune system to fight infections.

VERSAL may increase your risk of infections which can sometimes become serious.

- Your healthcare provider should check you for tuberculosis (TB) before you begin treatment with VERSAL and may treat you for TB if you have a history of TB or have TB.
- Your healthcare provider should watch you closely for signs and symptoms of TB during and after treatment with VERSAL.

What is VERSAL?

VERSAL is a prescription medicine used to treat adults:

- with moderate to severe plaque psoriasis and
- who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet or UV light)

It is not known if VERSAL is safe and effective in children under 18 years of age.

Who should not use VERSAL?

Do not use VERSAL if you have had a severe allergic reaction to bilibizumab or any of the other ingredients in VERSAL.

Before starting VERSAL, tell your HCP if you:

- are being treated for an infection
- have an infection that does not go away or that keeps coming back
- have TB or have been in close contact with someone with TB
- think you have an infection or have symptoms of an infection such as:
 - ◆ fever, sweats, or chills
 - ◆ muscle aches
 - ◆ cough
 - ◆ shortness of breath
 - ◆ blood in your phlegm (mucus)
 - ◆ weight loss
 - ◆ diarrhea or stomach pain
 - ◆ warm, red, or painful skin or sores on your body
 - ◆ burning when you urinate or urinate more often than usual
- have Crohn's disease or ulcerative colitis
- have recently or are scheduled to receive an immunization (vaccine). People who take VERSAL should not receive live vaccines. Prior to starting VERSAL, consider completion of all age appropriate immunizations according to current immunization guidelines
- are pregnant or plan to become pregnant. It is not known if VERSAL can harm your unborn baby
- are breastfeeding or plan to breastfeed. It is not known if VERSAL passes into your breast milk

After starting VERSAL, call your HCP right away if you have any of the symptoms of infection listed above.

Do not use VERSAL if you have any symptoms of infection unless you are instructed to by your HCP.

How should I use VERSAL?

See the detailed "Instructions for Use" that comes with your VERSAL for information on how to prepare and inject a dose of VERSAL, and how to properly throw away (dispose of) used VERSAL autoinjectors and prefilled syringes.

Tell your HCP about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of VERSAL?

VERSAL may cause serious side effects, including:

- See "What is the most important information I should know about VERSAL?"
- Serious allergic reactions. If you have a severe allergic reaction, do not give another injection of VERSAL. Get emergency medical help right away if you get any of the following symptoms of a serious allergic reaction:
 - ◆ trouble breathing or throat tightness
 - ◆ feeling faint
 - ◆ chest tightness
 - ◆ skin rash
 - ◆ swelling of your face, eyelids, lips, mouth, tongue, or throat
- **Crohn's disease or ulcerative colitis (Inflammatory bowel disease) can happen with VERSAL use, including worsening of symptoms.** Tell your HCP if you have new or worsening symptoms of inflammatory bowel disease during treatment with VERSAL, including: stomach pain, diarrhea (with or without blood), weight loss.

The most common side effects of VERSAL include: injection site reactions, upper respiratory infections, nausea, and fungal infection. These are not all of the possible side effects of VERSAL.

Tell your HCP about any side effect that bothers you or that does not go away. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For more information, call **1-800-545-5979** or go to the following website: **www.VERSAL.com**.