INDICATION

AUBAGIO® (teriflunomide) is indicated for the treatment of patients with relapsing forms of multiple sclerosis.

IMPORTANT SAFETY INFORMATION

WARNING: HEPATOTOXICITY AND RISK OF TERATOGENICITY

- Severe liver injury including fatal liver failure has been reported in patients treated with leflunomide, which is indicated for rheumatoid arthritis. A similar risk would be expected for teriflunomide because recommended doses of teriflunomide and leflunomide result in a similar range of plasma concentrations of teriflunomide. Concomitant use of AUBAGIO with other potentially hepatotoxic drugs may increase the risk of severe liver injury.

- Obtain transaminase and bilirubin levels within 6 months before initiation of AUBAGIO therapy. Monitor ALT levels at least monthly for 6 months after starting AUBAGIO. If drug-induced liver injury is suspected, discontinue AUBAGIO and start an accelerated elimination procedure with cholestyramine or activated charcoal. AUBAGIO is contraindicated in patients with severe hepatic impairment. Patients with pre-existing liver disease may be at increased risk of developing elevated serum transaminases when taking AUBAGIO.

- AUBAGIO is contraindicated for use in pregnant women and in women of reproductive potential who are not using effective contraception because of the potential for fetal harm. Teratogenicity and embryolethality occurred in animals at plasma teriflunomide exposure lower than that in humans. Exclude pregnancy before the start of treatment with AUBAGIO in females of reproductive potential. Advise females of reproductive potential to use effective contraception during AUBAGIO treatment and during an accelerated drug elimination procedure after AUBAGIO treatment. Stop AUBAGIO and use an accelerated drug elimination procedure if the patient becomes pregnant.

Please see additional Important Safety Information on page 5 and Full Prescribing Information, including boxed WARNING.

AUBAGIO is available in 14 mg and 7 mg tablets.
Transient, diffuse hair thinning/hair loss may be caused by many factors, including emotional and physiologic stress, autoimmune diseases, thyroid problems, vitamin deficiencies, inflammatory diseases, and certain drugs, including AUBAGIO® (teriflunomide).1,2

Based on observations of patients in clinical trials, the presentation of hair thinning/hair loss during AUBAGIO use is characteristic of resting-phase hair loss (telogen effluvium). The exact mechanism of hair thinning/hair loss during AUBAGIO use is not fully understood.

Hair thinning/hair loss can be a significant concern for patients, particularly female patients. The following talking points are designed to help you discuss this potential side effect with your patients.

Some patients experienced hair thinning/hair loss in AUBAGIO clinical trials4
• In clinical trials, up to 14% of patients treated with AUBAGIO experienced hair thinning/hair loss2

Most cases were mild to moderate and transient3
• No event was considered serious3
• Median time to onset was ~3 months3
• The average duration was less than 6 months3
• 87% of cases improved spontaneously while patients continued AUBAGIO therapy3

This side effect rarely led to discontinuation2-4
• In clinical trials, ~1% of patients discontinued AUBAGIO treatment due to hair thinning/hair loss2-4

Hair loss was NOT like chemotherapy-related hair loss3
• Hair thinning/hair loss in the clinical trials was described as diffuse and generalized over the scalp (ie, not patchy)3
• No cases of complete hair loss were reported in the entire clinical program3
• The presentation of hair thinning/hair loss during AUBAGIO use appears to be similar to the transient hair loss that can occur after pregnancy (telogen gravidarum)3,5,6

For more information on AUBAGIO, please visit AubagioHCP.com.
HAIR GROWS IN CYCLES, WITH PERIODS OF GROWTH AND REST

Hair changes associated with AUBAGIO® (teriflunomide) appear to be characteristic of resting-phase hair loss


Please see additional Important Safety Information on pages 1 and 5 and Full Prescribing Information, including boxed WARNING.
RESTING-PHASE HAIR LOSS

Resting-phase (telogen) hair loss

- Each normal hair follicle cycles independently so that some hairs are growing, others are resting, and others are shedding.\(^1\)
- In a normal hair cycle, we shed approximately 150 hairs per day.\(^1\)
- In resting-phase (telogen) hair loss, a greater number of hairs transition prematurely to the resting phase.\(^1,5\)
- These hairs fall out approximately 3 months later.\(^5\)
- Patients will usually notice an increased number of hairs beyond normal shedding on their hairbrush or in the shower and sometimes thinning of scalp hair.\(^5\)
- Hair grows back when follicles resume the normal hair cycle and start producing new hair.\(^5\)
Please see additional Important Safety Information on page 1 and Full Prescribing Information, including boxed WARNING.