



MOTRICAL®

Each Tablet contains:
Lamotrigine 100Mg Tablet

MOTRICAL
(lamotrigine) Tablets

MOTRICAL
(lamotrigine) Chewable Dispersible Tablets

MOTRICAL ODT
(lamotrigine) Orally Disintegrating Tablets

INDICATIONS :

MOTRICAL is used for the long-term treatment of bipolar I disorder to lengthen the time between mood episodes in people 18 years or older who have been treated for mood episodes with other medicine. It is not known if MOTRICAL is safe or effective in children or teenagers under the age of 18 with mood disorders such as bipolar disorder or depression

MOTRICAL is used, together with other medicines, to treat certain types of seizures (partial seizures, primary generalized tonic-clonic seizures, generalized seizures of Lennox-Gastaut syndrome) in people 2 years or older, or alone when changing from other medicines used to treat partial seizures in people =16 years. It is not known if MOTRICAL is safe or effective when used alone as the first treatment of seizures in adults

WARNING: SERIOUS SKIN RASHES :

MOTRICAL® can cause serious rashes requiring hospitalization and discontinuation of treatment. The incidence of these rashes, which have included Stevens-Johnson syndrome, is approximately 0.8% (8 per 1,000) in pediatric patients (2 to 16 years of age) receiving MOTRICAL as adjunctive therapy for epilepsy and 0.3% (3 per 1,000) in adults on adjunctive therapy for epilepsy. In clinical trials of bipolar and other mood disorders, the rate of serious rash was 0.08% (0.8 per 1,000) in adult patients receiving MOTRICAL as initial monotherapy and 0.13% (1.3 per 1,000) in adult patients receiving MOTRICAL as adjunctive therapy. In a prospectively followed cohort of 1,983 pediatric patients (2 to 16 years of age) with epilepsy taking adjunctive MOTRICAL, there was 1 rash-related death. In worldwide postmarketing experience, rare cases of toxic epidermal necrolysis and/or rash-related death have been reported in adult and pediatric patients, but their numbers are too few to permit a precise estimate of the rate.





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Other than age, there are as yet no factors identified that are known to predict the risk of occurrence or the severity of rash caused by MOTRICAL. There are suggestions, yet to be proven, that the risk of rash may also be increased by (1) coadministration of MOTRICAL with valproate (includes valproic acid and divalproex sodium), (2) exceeding the recommended initial dose of MOTRICAL, or (3) exceeding the recommended dose escalation for MOTRICAL. However, cases have occurred in the absence of these factors.

Nearly all cases of life-threatening rashes caused by MOTRICAL have occurred within 2 to 8 weeks of treatment initiation. However, isolated cases have occurred after prolonged treatment (e.g., 6 months). Accordingly, duration of therapy cannot be relied upon as means to predict the potential risk heralded by the first appearance of a rash.

Although benign rashes are also caused by MOTRICAL, it is not possible to predict reliably which rashes will prove to be serious or life-threatening. Accordingly, MOTRICAL should ordinarily be discontinued at the first sign of rash, unless the rash is clearly not drug-related. Discontinuation of treatment may not prevent a rash from becoming life-threatening or permanently disabling or disfiguring [see WARNINGS AND PRECAUTIONS]

MOTRICAL (lamotrigine), an AED of the phenyltriazine class, is chemically unrelated to existing AEDs. Its chemical name is 3,5-diamino-6-(2,3-dichlorophenyl)-as-triazine, its molecular formula is $C_9H_7N_5Cl_2$, and its molecular weight is 256.09. Lamotrigine is a white to pale cream-colored powder and has a pKa of 5.7. Lamotrigine is very slightly soluble in water (0.17 mg/mL at 25°C) and slightly soluble in 0.1 M HCl (4.1 mg/mL at 25°C). The structural formula is:





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MOTRICAL Tablets are supplied for oral administration as 25 mg (white), 100 mg (peach), 150 mg (cream), and 200 mg (blue) tablets. Each tablet contains the labeled amount of lamotrigine and the following inactive ingredients: lactose; magnesium stearate; microcrystalline cellulose; povidone; sodium starch glycolate; FD&C Yellow No. 6 Lake (100 mg tablet only); ferric oxide, yellow (150 mg tablet only); and FD&C Blue No. 2 Lake (200 mg tablet only).

MOTRICAL Chewable Dispersible Tablets are supplied for oral administration. The tablets contain 2 mg (white), 5 mg (white), or 25 mg (white) of lamotrigine and the following inactive ingredients: blackcurrant flavor, calcium carbonate, low-substituted hydroxypropylcellulose, magnesium aluminum silicate, magnesium stearate, povidone, saccharin sodium, and sodium starch glycolate.

MOTRICAL ODT Orally Disintegrating Tablets are supplied for oral administration. The tablets contain 25 mg (white to off-white), 50 mg (white to off-white), 100 mg (white to off-white), or 200 mg (white to off-white) of lamotrigine and the following inactive ingredients: artificial cherry flavor, crospovidone, ethylcellulose, magnesium stearate, mannitol, polyethylene, and sucralose.

MOTRICAL ODT Orally Disintegrating Tablets are formulated using technologies (Microcaps®* and AdvaTab®*) designed to mask the bitter taste of lamotrigine and achieve a rapid dissolution profile. Tablet characteristics including flavor, mouth-feel, after-taste, and ease of use were rated as favorable in a study of 108 healthy volunteers.

Important Safety Information About MOTRICAL® (lamotrigine) Tablets and MOTRICAL® ODT™ (lamotrigine) Orally Disintegrating Tablets

Prescription MOTRICAL Tablets are not for everyone. MOTRICAL ODT is another form of MOTRICAL.

MOTRICAL may cause a serious skin rash that may cause you to be hospitalized or to stop MOTRICAL; it may rarely cause death. There is no way to tell if a mild rash will develop into a more serious reaction. These serious skin reactions are more likely to happen when you begin taking MOTRICAL, within the first 2-8 weeks of treatment. But it can happen in people who have taken MOTRICAL for any period of time. Children between 2 to 16 years of age have a higher chance of getting this serious skin reaction while taking MOTRICAL.





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The risk of getting a rash is higher if taking MOTRICAL while taking valproate [Depakene* (valproic acid) or Depakote* (divalproex sodium)], taking a higher starting dose of MOTRICAL than a healthcare provider prescribed or increasing the dose of MOTRICAL faster than prescribed.

MOTRICAL can also cause other types of allergic reactions or serious problems which may affect organs and other parts of your body like the liver or blood cells. You may or may not have a rash with these types of reactions.

Call your healthcare provider right away if you have any of the following: a skin rash, hives, fever, swollen lymph glands, painful sores in the mouth or around the eyes, swelling of the lips or tongue, yellowing of the skin or eyes, unusual bruising or bleeding, severe fatigue or weakness, severe muscle pain or frequent infections.

These symptoms may be the first signs of a serious reaction. A healthcare provider should examine you to decide if you should continue taking MOTRICAL.

MOTRICAL may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Call a healthcare provider right away if you have worsening depression, any unusual changes in mood or behavior, or thoughts or actions about suicide or self-harm, especially if they are new, worse, or worry you (see Medication Guide).

You should not take MOTRICAL if you have had an allergic reaction to lamotrigine or to any of the inactive ingredients.

Common side effects include dizziness, headache, blurred or double vision, lack of coordination, sleepiness, nausea, vomiting, insomnia, tremor, rash, fever, abdominal pain, back pain, tiredness, and dry mouth. Tell your healthcare provider about any side effect that bothers you or does not go away. Also, tell your healthcare provider if you have any changes in your menstrual pattern, such as breakthrough bleeding, while taking MOTRICAL and birth control pills. These are not all the possible side effects of MOTRICAL.

Proven Efficacy With
ONCE-A-DAY Convenience
MOTRICAL® Xr™
(lamotrigine) Extended-Release Tablets





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*More common side effects may include: Blurred vision, dizziness, double vision, headache, nausea, rash, sleepiness, uncoordinated movements, vomitin

*Less common side effects may include: Abdominal pain, accidental injury, anxiety, constipation, depression, diarrhea, fever, "flu-like" symptoms, increased cough, inflammation of vagina, irritability, painful menstruation, sore throat, tremor

*Rare side effects may include: Absence of menstrual periods, chills, confusion, dry mouth, ear pain, emotional changes, heart palpitations, hot flashes, joint disorders, memory decrease, mind racing, muscle weakness, muscle spasm, poor concentration, ringing in ears, sleep disorder, speech disorder

*Additional side effects in children may include: Bronchitis, convulsions, ear problems, eczema, facial swelling, hemorrhage, infection, indigestion, light sensitivity, lymph node problems, nervousness, penis disorder, sinus infection, swelling, tooth problems, urinary tract infection, vertigo, vision problems

Why should this drug not be prescribed?

If you are sensitive to or have ever had an allergic reaction to MOTRICAL, you should not take this medication. Make sure your doctor is aware of any drug reactions you have experienced.

Special warnings about this medication

MOTRICAL may cause some people to become drowsy, dizzy, or less alert. Do not drive or operate dangerous machinery or participate in any activity that requires full mental alertness until you are certain the drug does not have this kind of effect on you. Remember to be alert for development of any type of rash, especially during the first 2 to 8 weeks of treatment.

Be sure to tell your doctor about any medical problems you have before starting therapy with MOTRICAL. If you have kidney or liver disease, or heart problems, MOTRICAL should be used with caution.

MOTRICAL may cause vision problems. If any develop, notify your doctor immediately. Also be quick to call your doctor if you develop a fever or have any other signs of an allergic reaction. Notify your doctor, too, if your seizures get worse. Possible food and drug interactions when taking this medication





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MOTRICAL is often combined with other medications used to treat epilepsy, including the following:

Carbamazepine (Tegretol)
Phenobarbital (Donnatal, Quadrinal, others)
Phenytoin (Dilantin)
Primidone (Mysoline)
Valproic acid (Depakene)

Be sure to check with your doctor before combining any other drugs with your seizure medications. MOTRICAL, in particular, may inhibit the action of sulfa drugs such as Bactrim, Proloprim, and Septra.

Special information if you are pregnant or breastfeeding

The effects of MOTRICAL during pregnancy have not been adequately studied. If you are pregnant or plan to become pregnant, tell your doctor immediately. MOTRICAL should be used during pregnancy only if clearly needed. MOTRICAL appears in breast milk. Because the effects of MOTRICAL on an infant exposed to this medication are unknown, breastfeeding is not recommended.





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Pronounced: LAM-ic-tal
Generic name: Lamotrigine

Full MOTRICAL Prescribing Information
Why is this drug prescribed?

MOTRICAL is prescribed to control partial seizures in people with epilepsy. It is also used to control a serious form of epilepsy known as Lennox-Gastaut syndrome. MOTRICAL is used in combination with other antiepileptic medications or as a replacement for a medication such as Tegretol, Dilantin, phenobarbital, or Mysoline. Most important fact about this drug

You may develop a rash during the first 2 to 8 weeks of MOTRICAL therapy, particularly if you are also taking Depakene. If this happens, notify your doctor immediately. The rash could become severe and even dangerous, particularly in children. A slight possibility of this problem remains for up to 6 months. How should you take this medication?

Take MOTRICAL exactly as prescribed by your doctor. Taking more than the prescribed amount can increase your risk of developing a serious rash. Do not stop taking this medication without first discussing it with your doctor. An abrupt halt could increase your seizures. Your doctor can schedule a gradual reduction in dosage.

If you miss a dose

Take it as soon as you remember. If it is almost time for your next dose, skip the one you missed and go back to your regular schedule. Do not take 2 doses at once.

Storage instructions

Store in a tightly closed container at room temperature. Keep dry and protect from light.

What side effects may occur?

Side effects cannot be anticipated. If any develop or change in intensity, tell your doctor as soon as possible. Only your doctor can determine if it is safe for you to continue taking MOTRICAL.

