

Product Name: PINRAL 50 mg chewable / disintegrating tablet

Active Substances: Lamotrigine

Form: 30 Tablets

Therapeutic indications: Epilepsy Adults (over 12 years of age) PINRAL is indicated in the treatment of epilepsy, partial seizures and generalized seizures, including tonic-clonic seizures and seizures associated with Lennox-Gastaut Syndrome, as an adjunct or monotherapy. and in generalized seizures, including tonic-clonic seizures and seizures associated with Lennox-Gastaut Syndrome, concomitant antiepileptic drugs (AEDs) can be discontinued after epileptic control is achieved during additional therapy and patients may continue with PINRAL monotherapy. Bipolar Disorder Adults (18 years of age and above) PINRAL is indicated for the prevention of mood episodes in patients with bipolar disorder, especially by preventing depressive episodes.

Posology and method of administration: "Adults (over 12 years old) Dosage in epilepsy monotherapy: In monotherapy, PINRAL starting dose is 25 mg once a day for the first two weeks, and 50 mg once a day for the following two weeks. Subsequently, the dose should be increased by a maximum of 50 to 100 mg every 1-2 weeks until optimal response is achieved. In order to achieve an optimal response, the maintenance dose is 100-200 mg / day once a day or in two divided doses. Some patients require 500 mg / day of lamotrigine to achieve the expected response. Starting dose and subsequent dose escalation should not be skipped due to the risk of rash (see Special warnings and precautions for use). Dose in the additional treatment of epilepsy: In patients who take valproate alone or in combination with any other antiepileptic drugs, PINRAL starting dose is 25 mg every other day for the first two weeks and 25 mg once a day for the following two weeks. Subsequently, the dose should be increased by a maximum of 25 to 50 mg every 1-2 weeks until optimal response is

achieved. In order to obtain an optimal response, the maintenance dose is 100-200 mg / day once a day or in two divided doses.

Antiepileptic drugs or other drugs that induce lamotrigine glucuronidation with or without other antiepileptic drugs (except valproate) or other drugs (see Other medical drugs.

3 interactions with products and other forms of interaction), the starting dose of PINRAL is 50 mg once a day for the first two weeks, and 100 mg / day in two divided doses for the following two weeks. Subsequently, the dose should be increased by a maximum of 100 mg every 1-2 weeks until optimal response is achieved. To obtain an optimal response, the maintenance dose is 200-400 mg / day, divided into two doses. Some patients require 700 mg / day lamotrigine to achieve the expected response. In patients taking medicines that do not significantly induce or inhibit lamotrigine glucuronidation, the starting dose of PINRAL is 25 mg once a day for the first two weeks and 50 mg once a day for the following two weeks (see Interactions with other medicinal products and other forms of interaction).

Subsequently, the dose should be increased by a maximum of 50 to 100 mg every 1-2 weeks until optimal response is achieved. In order to obtain an optimal response, the maintenance dose is 100-200 mg / day once a day or in two divided doses. Children (2 to 12 years old) The initial dose of lamotrigine as monotherapy in the typical absence seizure is 0.3 mg / kg / day, administered once or twice a day, and a total of 0.6 mg / kg / day for the next 2 weeks to be administered once or twice a day. The day is continued with the dose. Afterwards, the dose is increased to a maximum of 0.6 mg / kg every 1-2 weeks to reach the optimal dose. Generally, the maintenance dose with optimal response is 1-10 mg / kg / day once or twice a day; Some patients with typical absence seizures may require higher doses to achieve the desired response. In patients taking valproate alone or in combination with any other antiepileptic drug, PINRAL starting dose is 0.15 mg / kg / day once a day for the first two weeks, and 0.3 mg / kg / day once a day for the following two weeks. Subsequently, the dose should be increased by a maximum of 0.3 mg / kg every 1-2 weeks until optimal response is achieved. To obtain an optimal response, the maintenance

dose is 1-5 mg / kg / day once a day or in two divided doses, with a maximum of 200 mg / day. Antiepileptic drugs or other drugs that induce lamotrigine glucuronidation with or without other antiepileptic drugs (except valproate). (See Interactions with other medicinal products and other forms of interaction) In patients taking concomitantly, PINRAL starting dose is 0.6 mg / kg / day in two divided doses for the first two weeks and 1.2 mg / kg / day in two divided doses for the following two weeks. Subsequently, the dose should be increased by a maximum of 1.2 mg / kg every 1-2 weeks until optimal response is achieved. In order to obtain an optimal response, the maintenance dose is 5-15 mg / kg / day, divided into two doses with a maximum of 400 mg / day. In patients taking medicines that do not significantly induce or inhibit lamotrigine glucuronidation, the initial dose of PINRAL is once daily for the first two weeks or 0.3 mg / kg / day in two divided doses, then 0.6 mg / kg / day once a day for the following two weeks or in two divided doses. Then the dose should be increased by a maximum of 0.6 mg / kg every 1-2 weeks until an optimal response is achieved. In order to obtain an optimal response, the maintenance dose is 1-10 mg / kg / day, once a day or in two divided doses, with a maximum of 200 mg / day. Bipolar Disorder: Adults: a) Additional treatment with lamotrigine glucuronidation inhibitors, such as Valproate Valproate, in patients taking drugs that inhibit glucuronidation, the starting dose of PINRAL is 25 mg every other day for the first two weeks and 25 mg once a day for the following two weeks. The dose should be increased to 50 mg once a day (or two divided doses) in the 5th week. The target dose for optimal response is 100 mg / day once a day or in two divided doses. However, depending on the clinical response, the maximum daily dose may be increased up to 200 mg.

7b) Additional treatment with inducers of lamotrigine glucuronidation in patients NOT taking inhibitors such as valproate. This dosing regimen should be used with phenytoin, carbamazepine, phenobarbitone, primidone and other drugs known to induce lamotrigine glucuronidation (see Interactions with other medicinal products and other forms of interaction). In patients who are currently

taking medications that induce lamotrigine glucuronidation and do not take valproate, PINRAL initial dose is 50 mg once a day for the first two weeks, and 100 mg / day in two divided doses for the following two weeks. The dose should be increased to 200 mg / day in two divided doses in the 5th week. The dose can be increased to 300 mg / day in the 6th week, but the target dose is 400 mg / day in two divided doses, which can be given from the 7th week onwards, in order to obtain the optimal response. c) In patients receiving monotherapy with PINRAL or other drugs that do not significantly inhibit or induce lamotrigine glucuronidation, additional treatment PINRAL initial dose is 25 mg once a day for the first two weeks, and 50 mg once a day (or in two divided doses) for the following two weeks. The dose should be increased to 100 mg / day in the 5th week. The target dose for optimal response is 200 mg / day once a day or in two divided doses."