azurity pharmaceuticals

Horizant® gabapentin enacarbil extended-release tablets 600 mg·300 mg

SAMPLE LETTER OF MEDICAL NECESSITY

This sample letter and related information is provided for informational purposes only. It provides an example of the types of information that may be provided when responding to a request from a patient's health plan/insurer to provide a letter of medical necessity for _____. Health plan requirements may vary, so the prescriber should refer to the prior authorization or coverage information specific to their patient's health plan before completing a Letter of Medical Necessity. Use of the information in this letter does not guarantee coverage or that the health plan will provide reimbursement for _____ and is not intended to be a substitute for or to influence the independent medical judgment of the physician. It is the responsibility of the prescriber and/or their office staff, as appropriate, to determine the correct diagnosis, treatment protocol, and content of all such letters and related forms for each individual patient. The prescriber should refer to the Important Safety Information in the full Prescribing Information when determining whether the product is medically appropriate for a patient.

DRUG NAME

DRUG NAME

SAMPLE LETTER OF MEDICAL NECESSITY

Patient: _____

PATIENT NAME

Group/Policy Number: _____ Date(s) of service: _____

GROUP / POLICY NUMBER *DATE(S) OF SERVICE*

Diagnosis: _____

DIAGNOSIS CODE AND DESCRIPTION

Dear _____:

CONTACT NAME OR DEPARTMENT

I am writing on behalf of my patient, _____

PATIENT NAME

to _____

REQUEST PRIOR AUTHORZATION/DOCUMENT MEDICAL NECESSITY

for treatment with _____. _____

DRUG NAME *DRUG NAME*

is indicated for treatment of _____

INDICATION STATEMENT

This letter serves to document that _____ has a diagnosis of

PATIENT NAME

_____

DIAGNOSIS / CODE

and needs treatment with _____, and that _____ is

DRUG NAME *DRUG NAME*

medically necessary for _____ as prescribed. On behalf of _____,

HIM/HER *PATIENT NAME*

I am requesting approval for use and subsequent payment for the treatment with _____.

DRUG NAME

SUMMARY OF PATIENT MEDICAL HISTORY AND DIAGNOSIS

_____ is a _____-year-old _____.
PATIENT NAME *AGE* *MALE/FEMALE*

Diagnosed with _____.
DIAGNOSIS

_____ has been in my care since _____.
PATIENT NAME *DATE*

As a result of _____,
DIAGNOSIS

my patient _____.
ENTER BRIEF DESCRIPTION OF PATIENT HISTORY AND RECENT PRESENTATION

In my professional opinion, _____'s likely prognosis without treatment with
PATIENT NAME

_____, _____.
DRUG NAME *PROVIDE SUMMARY OF MEDICAL OPINION*

CLINICAL RATIONALE FOR _____
PRODUCT

Given the _____'s history, condition, and the supporting clinical information
PATIENT NAME

_____,
ATTACHED SUPPORTING MEDICAL RECORDS, LABORATORY REPORTS, ETC.

I believe treatment of _____ with _____ is warranted,
PATIENT NAME *PRODUCT*

appropriate and medically necessary. _____ is indicated for _____.
DRUG NAME *DRUG INDICATION*

The accompanying prescribing information provides the approved clinical information for _____.
DRUG NAME

The plan of treatment is to start the patient on _____,
DRUG NAME

_____.
PROVIDE TREATMENT COURSE

In summary, _____ is medically necessary and reasonable for _____'s
DRUG NAME *PATIENT NAME*

medical condition and warrants coverage. Please contact me at _____ if you require additional
PHYSICIAN TELEPHONE NUMBER

information about this case. Thank you for your prompt attention.

Sincerely,

_____, _____
PHYSICIAN NAME *PHYSICIAN DEGREE*

Important Safety Information for HORIZANT® (gabapentin enacarbil) Extended-Release Tablets

INDICATIONS:

HORIZANT® (gabapentin enacarbil) Extended-Release Tablets are indicated for the treatment of moderate-to-severe primary Restless Legs Syndrome (RLS) in adults. HORIZANT is not recommended for patients who are required to sleep during the daytime and remain awake at night.

HORIZANT® (gabapentin enacarbil) Extended-Release Tablets are indicated for the management of postherpetic neuralgia (PHN) in adults.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Effects on Driving

HORIZANT may cause significant driving impairment. The duration of driving impairment after starting therapy is unknown. Patients should not drive until they have enough experience on HORIZANT to know if it impairs their driving. Patients' ability to assess their driving competence and degree of somnolence caused by HORIZANT can be imperfect.

Somnolence/Sedation and Dizziness

HORIZANT causes somnolence/sedation and dizziness. Patients should not drive or operate other complex machinery until they have enough experience on HORIZANT to know if it impairs their ability to perform these tasks.

Lack of Interchangeability with Gabapentin

HORIZANT is not interchangeable with other gabapentin products because of differing pharmacokinetic profiles. The same dose of HORIZANT results in different plasma concentrations of gabapentin relative to other gabapentin products. The safety and effectiveness of HORIZANT in patients with epilepsy have not been studied.

Suicidal Behavior and Ideation

HORIZANT is a prodrug of gabapentin, an antiepileptic drug (AED). AEDs increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. As a prodrug of gabapentin, HORIZANT also increases this risk. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Anyone considering prescribing HORIZANT must balance the risk of suicidal thoughts or behavior with the risk of untreated illness.

Patients, caregivers, and families should be informed that HORIZANT increases the risk of suicidal thoughts and behavior and should be advised of the need to be alert for the emergence or worsening of the signs and symptoms of depression, any unusual changes in mood or behavior, or the emergence of suicidal thoughts, behavior, or thoughts of self-harm. Behaviors of concern should be reported immediately to healthcare providers.

Respiratory Depression

There is evidence from case reports, human studies, and animal studies associating gabapentin with serious, life-threatening, or fatal respiratory depression when co-administered with central nervous system (CNS) depressants, including opioids, or in the setting of underlying respiratory impairment. When the decision is made to co-prescribe HORIZANT with another CNS depressant, particularly an opioid, or to prescribe HORIZANT to patients with underlying respiratory impairment, monitor patients for symptoms of respiratory depression and sedation, and consider initiating HORIZANT at a low dose. The management of respiratory depression may include close observation, supportive measures, and reduction or withdrawal of CNS depressants (including HORIZANT).

Drug Reaction With Eosinophilia and Systemic Symptoms (DRESS)/Multiorgan Hypersensitivity

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as multiorgan hypersensitivity, has been reported in patients taking antiepileptic drugs, including gabapentin. HORIZANT is a prodrug of gabapentin. Some of these events have been fatal or life-threatening. DRESS typically, although not exclusively, presents with fever, rash, and/or lymphadenopathy, in association with other organ system involvement, such as hepatitis, nephritis, hematological abnormalities, myocarditis, or myositis sometimes resembling an acute viral infection. Eosinophilia is often present. Because this disorder is variable in its expression, other organ systems not noted here may be involved.

It is important to note that early manifestations of hypersensitivity, such as fever or lymphadenopathy, may be present even though rash is not evident. If such signs or symptoms are present, the patient should be evaluated immediately. HORIZANT should be discontinued if an alternative etiology for the signs or symptoms cannot be established.

Discontinuation of HORIZANT

When discontinuing HORIZANT, patients with RLS receiving 600 mg or less once daily can discontinue the drug without tapering. If the recommended dose is exceeded, the dose should be reduced to 600 mg daily for 1 week prior to discontinuation to minimize the potential of withdrawal seizure.

In patients with PHN receiving HORIZANT twice daily, the dose should be reduced to once daily for 1 week prior to discontinuation to minimize the potential of withdrawal seizure.

Tumorigenic Potential

In an oral carcinogenicity study, gabapentin enacarbil increased the incidence of pancreatic acinar cell adenoma and carcinoma in male and female rats. The clinical significance of this finding is unknown.

ADVERSE REACTIONS

The most common adverse reactions for patients with RLS (incidence >10% and at least 2 times the rate of placebo) were somnolence/sedation and dizziness.

The most common adverse reactions for patients with PHN (incidence >10% and greater than placebo) were dizziness, somnolence, and headache.

DRUG INTERACTIONS

Gabapentin enacarbil is released faster from HORIZANT Extended-Release tablets in the presence of alcohol. Consumption of alcohol is not recommended when taking HORIZANT.

HORIZANT taken in conjunction with morphine causes increased somnolence/sedation, dizziness, and nausea.

USE IN SPECIAL POPULATIONS

Pregnancy and Lactation

There are no adequate data on the developmental risk associated with the use of HORIZANT in pregnant women. In nonclinical studies in rats and rabbits, administration of gabapentin enacarbil was developmentally toxic when administered to pregnant animals at doses and gabapentin exposures greater than those used clinically.

It is not known whether gabapentin derived from HORIZANT is secreted in human milk; however, gabapentin is secreted into human milk following oral administration of other gabapentin products. There are no data on the effects of gabapentin on the breastfed infant or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for HORIZANT and any potential adverse effects on the breastfed infant from HORIZANT or from the underlying maternal condition.

Pediatric Use

Safety and effectiveness of HORIZANT in pediatric patients have not been studied.

Geriatric Use

Clinical trials of HORIZANT for the treatment of RLS did not include a sufficient number of patients 65 years and older to determine whether they respond differently from younger individuals. Because elderly patients are more likely to have decreased renal function, the frequency of dosing may need to be adjusted based on calculated creatinine clearance in these patients.

Renal Impairment

Gabapentin is known to be almost exclusively excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function. The dose of Horizant should be adjusted in patients with renal impairment based upon creatinine clearance. HORIZANT is not recommended for treatment of RLS in patients receiving hemodialysis.

Please see additional Important Safety Information throughout and full Prescribing Information, for HORIZANT.

To report SUSPECTED ADVERSE REACTIONS, contact Azurity Pharmaceuticals, Inc. at 1-800-461-7449, or FDA at 1-800-FDA-1088 or www.fda.gov/MedWatch.

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