PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

NYXE 5 mg, zolpidem tartrate 5 mg per tablet.

NYXE 10 mg zolpidem tartrate 10 mg per tablet.

Read all of this leaflet carefully before you start taking NYXE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- NYXE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT NYXE CONTAINS

The active substance is zolpidem tartrate.

NYXE 5 mg: Each film-coated tablet contains 5 mg zolpidem tartrate.

NYXE 10 mg: Each film-coated tablet contains 10 mg zolpidem tartrate.

The other ingredients are lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, hypromellose, macrogol 400 and titanium dioxide (C.I. No: 77891).

Contains sugar (lactose monohydrate).

2. WHAT NYXE IS USED FOR

Zolpidem is used to treat insomnia (trouble in sleeping). Zolpidem helps you get to sleep faster and sleep through the night. Zolpidem is only given when the disorder is severe, disabling or extremely distressing to the patient. Zolpidem should be used only for short periods of time.

3. BEFORE YOU TAKE NYXE

Do not take NYXE:

- if you are hypersensitive (allergic) to zolpidem or any of the other ingredients of NYXE
- if you suffer from myasthenia gravis (muscle disorder causing weakness)
- if you suffer from sleep apnoea (temporary stopping of breathing during sleep)
- if you suffer from lung disease
- if you have severe liver disease
- if you are under the age of 18 years
- if you are breastfeeding or pregnant. The safety of NYXE in pregnancy has not been established.

Take special care with NYXE:

- NYXE should be used for a short period of time, and generally for not longer than 4 weeks. Your doctor may want you to gradually reduce the amount you are taking before stopping completely.
- After repeated use of NYXE for a few weeks, some loss of the sleeping effect may develop.
- NYXE may cause a special type of memory loss or "amnesia". When this occurs, a person does not remember what has happened during the several hours between use of the medicine and the time when its effects wear off. This is usually not a problem since most people fall asleep after taking the medicine. In most instances, memory problems can be avoided by taking zolpidem only when you are able to get a full night's sleep (7 to 8 hours) before you need to be active again.
- After taking NYXE for insomnia, you may have difficulty sleeping (rebound insomnia) for the first few nights after you stop taking it. Mood changes, anxiety and restlessness may also occur. Rebound insomnia is more likely to occur if NYXE is stopped suddenly, and therefore the amount you are taking should be reduced gradually.
- Do not take more of NYXE, do not take it more often, and do not take it for a longer time than your doctor ordered. If too much is taken, it may become habit-forming (causing mental or physical dependence). If you have a history of alcohol or drug abuse, the risk of dependence increases. Once physical dependence as developed, sudden stopping of treatment will be accompanied by withdrawal symptoms. These may include headaches, muscle pain, extreme anxiety and tension, restlessness,

confusion and irritability. In severe cases, the following symptoms may occur: derealisation (altered experience of the external world so that it seems unreal), depersonalisation (subjective experience of unreality in one's sense of self), numbness and tingling of the limbs, hypersensitivity to light, noise and physical contact, hallucinations (seeing, hearing, or feeling things that are not there) or epileptic seizures.

- In older adults, the dose of zolpidem is reduced.
- Make sure you tell your doctor if you have breathing difficulties. Caution should be observed in these patients, since sleep tablets have been shown to impair respiratory drive.
- Make sure you tell your doctor if you suffer from depression, psychotic illness, or suicidal thoughts.
- Make sure you tell your doctor if you have a history of alcohol and drug abuse, since zolpidem should not be given to these patients.
- Make sure you tell your doctor if you have severe liver disease, since zolpidem should not be used to treat patients with severe liver disease.

Pregnancy and Breastfeeding:

- If zolpidem is given during the late phase of pregnancy, or during labour, the newborn may suffer from abnormally low body temperature, hypotonia (abnormally low muscle tone) and respiratory depression (abnormally slow and/or shallow breathing). Infants born to mothers who have taken zolpidem during pregnancy may develop physical dependence and may be at some risk of developing withdrawal symptoms.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking NYXE.

Driving and using machinery:

This medicine may cause some people to become drowsy, dizzy, or less alert than they are normally. Make sure you know how you react to zolpidem before you drive, use machines, or do anything else that could be dangerous if you are dizzy, or are not alert.

Important information about some of the ingredients of NYXE

Contains lactose. NYXE should not be taken by patients who have inherited problems such as intolerance to some sugars. Lapp lactose deficiency (this is when the body is unable to digest milk or milk products due to lack of an enzyme) or glucose-galactose malabsorption (this is when the small intestine is unable to absorb and transport the sugars glucose and galactose).

Taking other medicines with NYXE:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

- NYXE will add to the effects of alcohol and other CNS depressants (medicines that slow down the nervous system, possibly causing drowsiness). Some examples of CNS depressants are antihistamines or medicine for hay fever, other allergies; sedatives, tranquilizers, or sleeping medicine; prescription pain medicine or narcotics; medicine for seizures and anaesthetics.

  Check with your doctor before taking any of the above while you are using NYXE.

  NYXE should not be taken together with alcohol.
- Tell your doctor if you are taking rifampicin – The action of zolpidem is decreased when it is taken together with rifampicin.
- Tell your doctor if you are taking an HIV-protease inhibitor such as ritonavir – The blood level of zolpidem may be increased with a risk of extreme sedation and respiratory depression (abnormally slow and/or shallow breathing).

4. HOW TO TAKE NYXE

Do not share medicines prescribed for you with any other person.

Take NYXE only as directed by your doctor. Do not take it for a longer time than your doctor has ordered. The length of treatment varies from a few days to two weeks, with a maximum of four weeks. In certain cases, extension beyond the maximum treatment period may be necessary.

- NYXE should be taken immediately before going to bed, or in bed.
- **Dose:**

  Adults – 10 mg immediately before bedtime, or in bed.

Elderly or debilitated patients and in patients with liver disease – 5 mg immediately before bedtime, or in bed.

The total dose of zolpidem should not exceed 10 mg.

Always take NYXE exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of NYXE is too strong or too weak, talk to your doctor or pharmacist.

If you take more NYXE than you should:

Taking an overdose of zolpidem alone may lead to unconsciousness ranging from sleepiness to light coma. Overdose cases involving taking alcohol or other CNS depressants with zolpidem have resulted in more severe symptoms including fatal outcomes.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take NYXE:

If you miss a dose of NYXE, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

NYXE can have side effects.

Daytime drowsiness, confusion, headache, dizziness, loss of muscle co-ordination, clumsiness or unsteadiness, reduced alertness, fatigue, numbed emotions, muscle weakness, double vision.

These side effects mentioned above occur mainly at the start of therapy and most frequently in elderly patients, but may go away during treatment as your body adjusts to the medicine.

Other side effects include: Abdominal or stomach pain, diarrhoea, skin rashes, memory problems, mental depression, restlessness, agitation, irritability, aggressiveness, delusion, rages, nightmares, hallucinations (seeing, hearing, or feeling things that are not there), psychoses, inappropriate behaviour.

Not all side effects reported for NYXE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NYXE, please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF NYXE

Store in a dry place at or below 25 °C.

Store away from light.

Keep blisters in the original carton until required for use. Keep the HDPE container well closed.

Do not store in the bathroom, near the kitchen sink, or in other damp places. Moisture may cause the medicine to break down.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF NYXE

NYXE 5 mg, NYXE 10 mg:

1. Blister Packs:

Tablets are packed in blister packs composed of clear PVC / PVdC and printed silver-coloured aluminium foil. Each blister contains 10 tablets.

Pack size: 30's – Each carton contains 3 blisters of 10 tablets each.

2. HDPE Container Pack:

Tablets are packed in white opaque HDPE containers.

Pack size: 30's: One HDPE container of 30 tablets.

8. IDENTIFICATION OF NYXE

NYXE 5 mg: White to off – white, circular, biconvex, film – coated tablets, debossed with "E" on one side and "78" on the other side.

NYXE 10 mg: White to off – white, oval shaped, biconvex film – coated tablets, debossed with “E” on one side and debossed with “80” with a score line between “8” and “0” on the other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER

NYXE 5 mg: 43/2.2/0258

NYXE 10 mg: 43/2.2/0248

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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