PATIENT INFORMATION LEAFLET

MICRANIA MELTS RANGE

SCHEDULING STATUS

S4

MICRANIA MELTS 5 mg orodispersible tablets

MICRANIA MELTS 10 mg orodispersible tablets

Rizatriptan

MICRANIA MELTS is sugar-free

Each 5 mg tablet contains aspartame 1,450 mg

Each 10 mg tablet contains aspartame 2,90 mg

Read all of this leaflet carefully before you start taking MICRANIA MELTS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- MICRANIA MELTS 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.

What is in this leaflet

1. What MICRANIA MELTS is and what it is used for
2. What you need to know before you use MICRANIA MELTS
3. How to use MICRANIA MELTS
4. Possible side effects
5. How to store MICRANIA MELTS
6. Contents of the pack and other information

PATIENT INFORMATION LEAFLET

MICRANIA MELTS RANGE

1. What MICRANIA MELTS is and what it is used for

MICRANIA MELTS belongs to a class of medicines called triptans and is used to treat the headache phase of the migraine attack in adults.

Treatment with MICRANIA MELTS:

- reduces widening of blood vessels surrounding the brain. This widening results in the headache pain of a migraine attack.
- blocks the release of substances from nerve endings that cause more pain and other symptoms of migraine.
- interrupts the sending of specific pain signals to your brain.

2. What you need to know before you take MICRANIA MELTS

Do not take MICRANIA MELTS:

- if you are hypersensitive (allergic) to rizatriptan, or to any of the ingredients of MICRANIA MELTS (see section 6)
- if you are currently taking medicines called monoamine oxidase (MAO) inhibitors (e.g. moclobemide, phenelzine, tranylcypromine, linezolid or pargyline) to treat depression, or if it has been less than two weeks since you stopped taking a MAO inhibitor
- if you have high blood pressure which is not controlled by medication
- if you have heart disease or have a history of heart disease including heart attack or pain on the chest (angina)
- if you have had a stroke or mini stroke
- if you have blockage problems with your arteries, including ischaemic bowel disease (chronic inflammation of your digestive tract, where the blood flow to your bowel is blocked or cut off and your intestines don't have the oxygen needed to work correctly)
- if you are taking ergotamine-type medications, such as ergotamine or dihydro-ergotamine to treat

your migraine or methysergide to prevent a migraine attack. Ask your doctor, pharmacist or other health care provider if you are not sure

- if you are pregnant or breastfeeding your baby
- children under the age of 18 years of age.

Warnings and precautions

Take special care with MICRANIA MELTS:

Tell your doctor or health care provider:

- if your headache is associated with dizziness, difficulty in walking, lack of coordination or weakness in the leg and arm
- if you have any of the following risk factors for heart disease: high blood pressure, diabetes (high blood sugar), you are a smoker or using nicotine substitutes, you have a family history of heart disease, you are a man over 40 years of age or you are a post-menopausal woman
- if you are taking any other medicines for migraine (e.g. sumatriptan)
- if you have short lived symptoms including chest pain and tightness
- if you are taking medicines called selective serotonin reuptake inhibitors (SSRIs) such as sertraline, escitalopram oxalate, and fluoxetine or serotonin norepinephrine reuptake inhibitors (SNRIs) such as venlafaxine, and duloxetine for depression
- if you are taking a medicine called propranolol for (used to treat heart problems, help with anxiety, prevent migraines or high blood pressure) as this may affect the way
  MICRANIA MELTS works
- if you use herbal preparation containing St. John's Wort
- you have had allergic reaction like swelling of face, lips, tongue and/or throat which may cause difficulty breathing and/or swallowing (angioedema).

If you take MICRANIA MELTS too often this may result in you getting a chronic headache. In such cases you should contact your doctor as you may have to stop taking MICRANIA MELTS.

Tell your doctor or pharmacist about your symptoms. You should take MICRANIA MELTS only when your doctor has told you that you have migraine attacks. MICRANIA MELTS should not be used to treat headaches that might be caused by other, more serious conditions.

Other medicines and MICRANIA MELTS

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

You should tell your doctor if you are taking any of the following medicines, because you should not take MICRANIA MELTS together with these medicines:

- ergotamine-type medicines such as ergotamine, dihydro-ergotamine or methysergide) to treat or prevent your migraine. You should wait at least 6 hours after taking MICRANIA MELTS before you take these medicines
- other medicines in the same class called 5-$HT_{1B/1D}$ agonists (sometimes referred to as ‘triptans’) such as sumatriptan, zolmitriptan and naratriptan (see Do not take MICRANIA MELTS)
- if you are taking a monoamine oxidase (MAO) inhibitor such as moclobemide, phenelzine, tranylcypromine, linezolid, or pargyline or if it has been less than two weeks since you stopped taking an MAO inhibitor (see Do not take MICRANIA MELTS).

Tell your doctor if you are taking any of the following medicines as these medicines may increase your risk of getting side-effects when you take it together with MICRANIA MELTS:

- propanolol (a beta blocker to treat heart problems)

- selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs) for depression.

MICRANIA MELTS with food and drink

MICRANIA MELTS can take longer to work if it is taken after food. Although it is better to take it on an empty stomach, you can still take it if you have eaten.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using MICRANIA MELTS.

Do not take MICRANIA MELTS if you are pregnant or breastfeeding.

Driving and using machines

You may feel sleepy or dizzy while taking MICRANIA MELTS.
It is not always possible to predict to what extent MICRANIA MELTS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MICRANIA MELTS affects them.

MICRANIA MELTS contains aspartame

MICRANIA MELTS contains aspartame, a source of phenylalanine which may be harmful to people with phenylketonuria (a rare inherited disorder that causes an amino acid called phenylalanine to build up in the body).

3. How to take MICRANIA MELTS

Do not share medicines prescribed for you with any other person. Always use MICRANIA MELTS

exactly as your doctor has told you. You should check with your doctor, pharmacist or other health care provider if you are not sure.

Adults:

The usual dose is 5 mg to 10 mg MICRANIA MELTS.

Doses of MICRANIA MELTS should be taken at least 2 hours apart and not more than 30 mg MICRANIA MELTS should be taken in any 24 hour period.

If your migraine returns within 24 hours, take an additional dose of MICRANIA MELTS, however always wait at least 2 hours between doses.

If you do not respond to the first dose of MICRANIA MELTS during a migraine attack, you should not take a second dose of MICRANIA MELTS to treat the same attack. It is still likely, however, that you will respond to MICRANIA MELTS during the next migraine attack.

If you are currently taking propanolol you should take MICRANIA MELTS 5 mg up to a maximum of 3 x 5 mg doses (15 mg) in a 24-hour period.

MICRANIA MELTS need not be taken with liquid. Do not remove the tablet from the blister until you need to take it. The tablet should be removed from the blister with dry hands and placed on the tongue, where it will dissolve and be swallowed with the saliva.

Your doctor will tell you how long your treatment with MICRANIA MELTS will last.

If you have the impression that the effect of MICRANIA MELTS is too strong or too weak, tell your doctor or pharmacist.

If you take more MICRANIA MELTS than you should

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

Symptoms of overdose may include:

- feeling dizzy and drowsy, vomiting, inability to control your bladder, high blood pressure, fainting and slow heart rate.

4. Possible side effects

MICRANIA MELTS can have side effects.

Not all side effects reported for MICRANIA MELTS are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using MICRANIA MELTS, please consult your health care provider for advice.

If any of the following happens, stop using MICRANIA MELTS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MICRANIA MELTS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- seizures (fits)

- "serotonin syndrome" that may cause side effects like coma, unstable blood pressure, extremely high body temperature, lack of muscle coordination, agitation and hallucinations
- rapid, strong, irregular or slow heartbeat, abnormalities of the electrocardiogram (a test that records the electrical activity or your heart), heart attack
- spasm of the blood vessels of the heart (these generally occur in patients with risk factors for heart and blood vessel disease).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- problems sleeping (insomnia)
- dizziness, sleepiness, headache, pins and needles, decreased mental sharpness, decreased sensitivity of the skin
- hot flushes or flashes
- throat discomfort
- nausea, dry mouth, vomiting, indigestion, upper abdominal discomfort, diarrhoea
- sweating, flushing
- stiffness, feeling of heaviness or tightness in parts of the body
- chest pain, abdominal pain
- lack of energy, extreme tiredness.

Less frequent side effects:

- disorientation, nervousness
- unsteadiness when walking (ataxia), vertigo (spinning sensation when standing still), distortion of taste, bad taste in the mouth, tremor
- blurred vision

- high blood pressure
- shortness of breath, wheezing
- thirst
- severe itching of the skin (pruritus), swelling of face, lips, tongue and/or throat which may cause difficulty breathing and/or swallowing (angioedema), rash
- neck pain, stiffness, muscle weakness, feeling of tightness in parts of the body, muscle pain, facial pain.

The following side effects have been reported but the frequency for them to occur is not known:

- spasm of blood vessels of the extremities including coldness and numbness of the hands or feet
- spasm of the blood vessels of the colon (large bowel), which can cause abdominal pain
- severe shedding of the skin with or without fever (toxic epidermal necrolysis).

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. T You can also report any side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link "https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of MICRANIA MELTS.

5. How to store MICRANIA MELTS

Store all medicines out of reach of children.

Store at or below 25 °C

Do not remove the tablet from the blister until just prior to dosing.

Keep blister in carton until required for use.

Do not use after the expiry date stated on the carton. Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What MICRANIA MELTS contains

The active ingredient is rizatriptan benzoate.

MICRANIA MELTS 5 mg: Each tablet contains 7,265 mg rizatriptan benzoate, equivalent 5 mg rizatriptan.

MICRANIA MELTS 10 mg: Each tablet contains 14,35 mg rizatriptan benzoate, equivalent 10 mg rizatriptan.

MICRANIA MELTS is sugar free.

MICRANIA MELTS 5 mg: Each tablet contains aspartame 1,450 mg.

MICRANIA MELTS 10 mg: Each tablet contains aspartame 2,90 mg.

The other ingredients are:

Aspartame, magnesium stearate, maize starch, microcrystalline cellulose, mint powder, silica colloidal anhydrous.

What MICRANIA MELTS looks like and contents of the pack

MICRANIA MELTS 5 mg: White, round, biconvex tablets.

MICRANIA MELTS 10 mg: White, round, biconvex tablets with score line on one side.

The score line on the 10 mg tablet is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Aluminium foil blister strip containing either 3 or 6 tablets, packed in an outer carton.

Holder of Certificate of Registration

Pharma Dynamics (Pty) Ltd

1st Floor, Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, Cape Town

7945, South Africa

Tel: +27 21 707 7000

www.pharmadynamics.co.za

This leaflet was last revised in

March 2022

Registration number

MICRANIA MELTS 5 mg*: A51/7.3/0561

MICRANIA MELTS 10 mg: A51/7.3/0562

*Not all strengths may be marketed.