

WELEDA RELAXING ORAL DROPS**WELEDA**

HOMEOPATHIC MEDICINAL PRODUCT

PATIENT INFORMATION

Read this leaflet carefully because it contains important information for you. Keep this leaflet as you may need to read it again.

Ask your qualified healthcare practitioner or healthcare professional e.g. a doctor or pharmacist if you need more information or advice.

You must talk to a doctor if you feel worse, or do not feel better after seven days. If you get any side-effects, talk to your qualified healthcare practitioner or healthcare professional e.g. a doctor or pharmacist. This includes any possible side-effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What this product is and what it is used for
2. What you need to know before taking this product
3. How to take this product
4. Possible side-effects
5. How to store this product
6. Contents of the pack and other information

1. What this product is and what it is used for

Weleda Relaxing Oral Drops is a homeopathic medicinal product used within the homeopathic tradition for the temporary relief of mild symptoms associated with stress and to aid sleep.

2. What you need to know before taking this product**• Do not take:**

- if you are allergic to any of the ingredients (see Section 6)
- if you are under 18 years of age
- if you are taking any other medicines that interact with alcohol e.g. metronidazole, disulfiram
- if you are taking other medicines to help you sleep, relieve anxiety or make you feel sleepy.

• Warnings and precautions:

This product is intended for the temporary relief of symptoms associated with mild stress. Consumers with signs and symptoms of depression should seek medical advice for appropriate treatment.

This product contains alcohol. The amount of alcohol in each 1ml is 357mg. The small amount of alcohol in this medicine will not have any noticeable effects.

The maximum recommended dose of this medicinal product (5ml) will increase the concentration of alcohol in your body by approximately 380mg/L. This is equivalent to drinking 47.5ml of beer or 19.5ml of wine.

Alcohol may increase the effect of this product. Excessive use of alcohol whilst taking this product should be avoided.

Not to be used repeatedly without consulting a doctor. If your symptoms worsen, or persist after seven days of taking this product talk to your doctor or qualified healthcare professional.

• Pregnancy and breastfeeding

- do not take this product if you are pregnant or breastfeeding.

• Driving and using machines

- do not drive or operate machinery if you feel dizzy, tired or if you are affected by this medicine.

3. How to take this product

Always take this medicine exactly as described in this leaflet or as your qualified healthcare practitioner or healthcare professional e.g. a doctor or pharmacist has told you. Check with them if you are not sure.

Directions for use: for oral use only.

Check the recommended dose to see how much medicine to use.

How to use the dropper:

- Unscrew the cap by pushing the cap down and twisting in an anti-clockwise direction
- Hold the bottle upright and place the dropper inside the bottle
- Squeeze the bulb to draw the amount of solution required into the dropper to either the 0.75ml or 1ml marking on the side of the dropper as appropriate (see the recommended dose section for the correct dose)
- If too much solution is drawn up into the dropper gently squeeze the bulb to release the solution back into the bottle until the correct dose has been measured
- If too little solution has been drawn up, replace the dropper into the bottle and gently squeeze to draw up more solution
- After use, screw the dropper back onto the bottle.

The recommended dose is:**Adults from 18 years of age and the elderly:**

Temporary relief of mild stress symptoms: add 0.75ml to 1ml to a small amount of water, three times a day.

To aid sleep: add 1ml to 2ml to a small amount of water, half an hour before retiring to bed.

The maximum daily dose is 5ml. Do not exceed the stated dose.

If you take more Weleda Relaxing Oral Drops than you should

- If you take more of Weleda Relaxing Oral Drops than you should and you feel unwell, consult your doctor.

If you forget to take Weleda Relaxing Oral Drops

- If you miss a dose of Weleda Relaxing Oral Drops just take the next dose as usual. Do not take another dose to make up for the missed dose.

If you have any further questions on the use of this medicine, ask your qualified healthcare practitioner or healthcare professional e.g. doctor or pharmacist.

4. Possible side-effects

Like all medicines, this product can have side-effects, although not everybody gets them. The following side effects have been reported with Valerian root preparations:

Nausea (feeling sick)

Vomiting

Abdominal Cramps

Abdominal pain

Diarrhoea

Dizziness

Headache

Nightmares or vivid dreams.

If these persist for more than a few days or become troublesome, stop taking this product.

Other side-effects: One case of hypersensitivity and one case of nausea and tachycardia have been reported after taking much higher levels of Passion Flower herb preparations.

If you notice any side-effects or if symptoms worsen or persist consult your qualified healthcare practitioner or professional e.g. doctor or pharmacist.

Reporting of side-effects: If you get any side-effects, talk to your qualified healthcare practitioner or healthcare professional e.g. a doctor or pharmacist. This includes any possible side-effects not listed in this leaflet. By reporting side-effects you can help provide more information on the safety of this medicine.

Reporting of side-effects in the UK:

You can help to make medicines safer by reporting any side-effects to the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store.

5. How to store this product

- Keep out of the sight and reach of children
- Do not store above 25°C. Store in the original container
- Keep the container in the outer carton
- Do not use after the expiry date on the carton and label
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Weleda Relaxing Oral Drops contains: Each ml of oral drops contains: *Avena sativa* mother tincture 0.25ml [equivalent to 121mg fresh *Avena sativa* herb], Extraction solvent: Ethanol 62% w/w, *Humulus lupulus* mother tincture 0.04ml [equivalent to 3mg Hops Strobile], Extraction solvent: Ethanol 86% w/w, *Passiflora incarnata* mother tincture 0.075ml [equivalent to 23mg fresh Passion Flower herb], Extraction solvent: Ethanol 86% w/w, *Valeriana officinalis* mother tincture 0.3ml [equivalent to 26mg Valerian root], Extraction solvent: Ethanol 43% w/w, *Coffea tosta* 60X 0.15ml.

What Weleda Relaxing Oral Drops, solution looks like and contents of the pack: This medicine is a clear, yellow-brown liquid. It is presented in a violet glass bottle with dropper incorporating a child resistant and tamper-evident cap. Pack sizes are 25, 50 and 100ml. Not all pack sizes may be marketed.

NR holder and manufacturer: Weleda (UK) Ltd, Heanor Road, Ilkeston, Derbyshire DE7 8DR.
NR 00298/0298.

Braille version

To request a copy of this leaflet in Braille, or large print or to listen to an audio version, please call, free of charge: 0800 198 5000 (UK only).

Please be ready to give the following information:

Product name: Weleda Relaxing Oral Drops

Reference number NR 00298/0298

This service is provided by the Royal National Institute of Blind people.

Weleda Relaxing Oral Drops contains homeopathic mother tinctures and a high dilution of a homeopathic stock prepared in Anthroposophic tradition.

For further information concerning homeopathic medicines contact:

British Homeopathic Association, CAN Mezzanine, 49-51 East Road, London N1 6AH.

For further information on anthroposophic medicines contact:

PAFAM, c/o Cathie Green, Woodstone Oast House, Woodston, Tenbury Wells, Worcestershire WR15 8JG