

MEDICA PACKAGING PROOF APPROVAL

PLEASE CHECK THIS PROOF CAREFULLY FOR CONTENT, TEXT, SPELLING, LAYOUT, PANEL ORIENTATION, VARNISH FREE AREA, SIZE, COLOUR REFERENCES AND COLOUR SEPARATIONS ETC. MEDICA PACKAGING CANNOT ACCEPT LIABILITY FOR ANY ERRORS OVERLOOKED ONCE THIS PROOF HAS BEEN SIGNED AND RETURNED. TO CONFIRM YOUR APPROVAL PLEASE SIGN BELOW AND RETURN.

Name	Position	Sign	Date
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Irish Botanica®
Peace & Calm
Oral Liquid
Valerian Tincture

Patient Information Leaflet

Read all of this leaflet
carefully before
you start using this
medicine because
it contains important
information for you.

Always use this medicine exactly as described in this leaflet or as your doctor, or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

What is in this leaflet

1. What this product is and what it is used for
2. What you need to know before you take 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

The Active ingredient is valerian root. Irish Botanica Peace & Calm is a traditional herbal medicinal product used in adults for the relief of symptoms of mild mental stress and to aid sleep, exclusively based on long-standing use.

2. Before you take this product

Do not take this product if you are allergic to any of the ingredients (see section 6).

Warnings and precautions

Do not exceed the recommended dosage. This product may cause drowsiness.

Children and adolescents

Do not give this product to children or adolescents under the age of 18 years as it is not known if it is safe to do so and medical advice should be sought.

Other medicines and Irish Botanica Peace & Calm

Do not take this product if you are already taking a medicine which can cause drowsiness. Do not take this product if you are already taking another medicine which is affected by alcohol.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medication including other herbal medicines or medicines that didn't require a prescription.

Irish Botanica Peace & Calm with food, drink and alcohol

Alcohol may increase the effects of this product. This product contains alcohol (see below for details of alcohol content). Excessive use of alcohol should therefore be avoided.

Pregnancy and breast-feeding

Do not take this product if you are pregnant, breast-feeding or planning to have a baby as it is not known if it is safe to do so.

Driving and using machines

This product may impair the ability to drive or use machinery. Affected patients should not drive or operate machinery. This product contains alcohol (see below for details of alcohol content).

Overdose of this product may result in alcohol intoxication.

Irish Botanica Peace & Calm contains

Liquorice Liquid Extract
Sweet Orange Oil
Lemon Oil
Coriander Oil
Star Anise Oil
Ethanol (Alcohol)
Sucrose
Water

This medicine contains 1780 mg of alcohol (ethanol) in each 5 ml dose, which is equivalent to 45 ml beer or 19 ml wine per 5 ml dose. The amount of alcohol in this medicine is not likely to have an effect in adults. The alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines. If you are pregnant or breast feeding, talk to your doctor or pharmacist before taking this medicine. If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine. Sucrose: This medicine contains 734 mg of sucrose per 5 ml dose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May be harmful to the teeth.



3. How to take this product

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For oral short-term use only.

Adults and the elderly:

For the symptomatic relief of mild mental stress: Take one 5ml spoonful three times a day with water or fruit juice if desired.

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Patient Information Leaflet

To aid sleep: Take one 5ml spoonful 30 minutes before bedtime with an earlier dose during the evening if necessary.
The effects of this treatment may not occur immediately, therefore this product should be taken continuously for 2 weeks.

Do not exceed the stated dose.
This product is not suitable for children or those under 18.

Maximum daily dose: Four single doses.

If you take more of this product than you should
If you take more than the recommended dose, speak to a doctor or pharmacist and take this leaflet with you. Overdose of this product may result in alcohol intoxication and should be treated accordingly. (See Section 2 for alcohol content)

If you forget to take this product
Continue to take your usual dose at the usual time. It does not matter if you have missed a dose. Do not take a double dose to make up for a forgotten dose.
If your symptoms of mild mental stress and or sleeplessness **worsen or persist after you have taken the product for two weeks tell your doctor.**
If you have any questions on the use of this medicine, please ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this product can have side effects, although not everybody gets them. These include:

- Nausea
- Stomach cramps

The frequency of the above side effects isn’t known. If these persist or become troublesome stop taking the product.
Tell your doctor or pharmacist if you notice any other side effects.

Reporting of side effects
If you get any side-effects, talk to your doctor, pharmacist or nurse. This includes any possible side-effects not listed in this leaflet. You can also report side-effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie.

By reporting side-effects, you can help provide more information on the safety of this medicine.

5. How to store this product

Do not use this product after the expiry date stated on the bottle and carton. The expiry date refers to the last day of that month.
Return any out of date medicine to your pharmacist who will dispose of it for you.
This product does not require any special storage conditions. Keep the bottle tightly closed.
Keep all medicines out of the reach and sight of children.


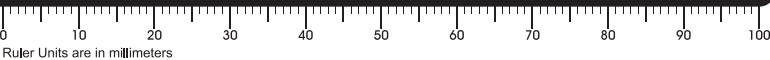
6. Further information

Irish Botanica Peace & Calm is a brown liquid.
Ingredients: Each 5ml of oral liquid contains 2ml of tincture from dried *Valeriana officinalis* L., radix (Valerian root) (DER 1:2). Extraction solvent ethanol 60% v/v.
This product also contains the following ingredients: Liquorice Liquid Extract, Sweet Orange Oil, Lemon Oil, Coriander Oil, Star Anise Oil, Ethanol (96%), Sucrose, Water.
This product is available in packs of 100ml & 200ml.
Traditional Herbal Registration Holder:
Irish Botanica, 3-5, Charvey Business Park, Rathnew, Co. Wicklow, Ireland.

Manufacturer:
Rutland Biodynamics Ltd., Town Park Farm, Brooke, Rutland LE15 8DG, United Kingdom.
Traditional herbal registration number: TR1723/2/1.
If you would like further information about this product.
Contact: Irish Botanica, 3-5, Charvey Business Park, Rathnew, Co. Wicklow, Ireland.

Leaflet prepared December 2022

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