



HERBAL PRACTITIONER'S GUIDE TO HERBS LISTED IN **SCHEDULE 20** OF THE HUMAN MEDICINES REGULATIONS 2012

Last updated April 2022



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Introduction

The basis of UK medicines law is The Human Medicines Regulations 2012, which is administered by the Medicines and Healthcare Products Regulatory Agency (MHRA).

This updates and supersedes earlier legislation such as the Medicines Act 1968 and the Traditional Herbal Medicinal Products Directive (THMPD).

The complete text can be found online at

<https://www.legislation.gov.uk/uksi/2012/1916/contents/made>

Summary

Regulation 241 of the Human Medicines Regulations 2012 states that the herbs listed in Part 2 of Schedule 20 (commonly referred to as 'Schedule 20 herbs' or 'Schedule 3 herbs') may be used by herbalists if and only if the following conditions are met:

- Products for internal use must be clearly labelled with a dosage that will provide no more than the maximum daily dose specified for that herb. Products for external use must contain no more than the specified maximum percentage of the herb in the product
- The product is not manufactured on a large scale or by an industrial process
- They are offered for sale or supply from premises occupied by the practitioner and from which the practitioner can exclude the public
- The practitioner must have been requested by or on behalf of the patient and in that patient's presence to exercise their professional judgment as to the treatment required.

The herbs listed in Part 2 have been in use by herbal practitioners for many decades. In 1974 almost every Member of the National Institute of Medical Herbalists completed a questionnaire about the remedies they were using and the average dosage given.

The maximum dose recommended for each herb in Schedule 20 approximates to the average amount being prescribed by Members as reported in that questionnaire

Tincture ratios

The weight: volume system of calculating tincture ratios is based on the idea that a given volume of tincture could be considered to be equivalent to a given weight of the dried herb. So a 1:1 tincture indicates that 1g of the dried herb is equivalent to 1ml of tincture. A 1:2 indicates that 1g is equivalent to 2ml of tincture; and so on.

In 2021, the BHMA initiated a project to harmonise the ratios being used in the manufacture of Schedule 20 tinctures by different suppliers to the herbal profession.

THEREFORE SOME RATIOS FROM YOUR USUAL SUPPLIER MAY BE CHANGING

In practice, there are many factors that will cause the levels of active constituents in a tincture to fall well below that suggested by the weight:volume ratio. For example

- The volume part of a ratio may indicate either the quantity of macerate initially added when using a 'starting spec' method, or the quantity of tincture extracted when the marc is pressed as in an 'ending spec'
- The use of fresh herb will result in very different products from dried herb products. The two cannot be directly compared
- The choice of extraction method will influence the degree to which the marc is exhausted. For example, percolation will usually extract more than maceration. Therefore they will produce tinctures with different levels of active constituents

ADVICE TO PRACTITIONERS

Practitioners should

- Check the ratio of the tincture even if using the same supplier as in the past
- Use an appropriate maximum dosage for the current ratio
- Take extra care with existing prescriptions when your stock of any Schedule 20 herb changes from one supplier to another



Maximum tincture dosages: Herbs for internal use

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| Botanical source | Common name | Part used | Tincture ratio | Max single dose of tincture | Max daily dose of tincture | Max weekly dose of tincture |
|---|-----------------------------------|-------------------------|----------------|-----------------------------|----------------------------|-----------------------------|
| <i>Adonis vernalis</i> | False Hellebore Pheasant's eye | Herb | 1:10 | 1ml | 3ml | 20ml |
| <i>Aspidosperma quebrachoblanco</i> | Quebracho | Dried bark | 1:5 | 0.25ml | 0.75ml | 5ml |
| <i>Atropa acuminata</i> <i>Atropa belladonna</i> | Deadly nightshade | Herb | 1:10 | 0.5ml | 1.5ml | 10ml |
| <i>Atropa acuminata</i> <i>Atropa belladonna</i> | Deadly nightshade | Root | 1:10 | 0.3ml | 0.9ml | 6ml |
| <i>Chelidonium majus</i> | Greater celandine | Aerial parts | 1:5 | 10ml | 30ml | 210ml |
| <i>Cinchona calisaya</i> <i>Cinchona ledgerana</i> <i>Cinchona micrantha</i> <i>Cinchona officinalis</i> <i>Cinchona succirubra</i> | Cinchona bark Peruvian Bark | Bark | 1:10 | 2.5ml | 7.5ml | 50ml |
| <i>Colchicum autumnale</i> | Meadow saffron | Corm | 1:10 | 1ml | 3ml | 20ml |
| <i>Convallaria majalis</i> | Lily of the Valley | Leaf | 1:5 | 0.75ml | 2.25ml | 15ml |
| <i>Convallaria majalis</i> | Lily of the Valley | Leaf | 1:8 | 1.2ml | 3.6ml | 25ml |
| <i>Datura innoxia</i> <i>Datura stramonium</i> | Thorn apple Stramonium | Leaf and flowering tops | 1:10 | 0.5ml | 1.5ml | 10ml |
| <i>Ephedra distachya</i> <i>Ephedra equisetina</i> <i>Ephedra gerardiana</i> <i>Ephedra intermedia</i> <i>Ephedra sinica</i> | Ephedra Ma Huang | Young stems | 1:5 | 3ml | 9ml | 60ml |
| <i>Ephedra distachya</i> <i>Ephedra equisetina</i> <i>Ephedra gerardiana</i> <i>Ephedra intermedia</i> <i>Ephedra sinica</i> | Ephedra Ma Huang | Young stems | 1:4 | 2.4ml | 7.2ml | 50ml |
| <i>Gelsemium sempervirens</i> | Gelsemium Yellow Jasmine | Rhizome and root | 1:10 | 0.25ml | 0.75ml | 5ml |
| <i>Hyoscyamus albus</i> <i>Hyoscyamus muticus</i> <i>Hyoscyamus niger</i> | Henbane | Leaf and inflorescence | 1:10 | 1ml | 3ml | 20ml |
| <i>Lobelia inflata</i> | Lobelia | Leaves and tops | 1:5 | 1ml | 3ml | 20ml |
| <i>Lobelia inflata</i> | Lobelia | Leaves and tops | 1:8 | 1.6ml | 4.8ml | 30ml |



Maximum concentrations: Herbs for external use only

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| Botanical source | Common name | Part used | Tincture ratio | Maximum percentage allowed in cream or ointment |
|---|-------------|---|----------------|---|
| <i>Aconitum balfourni</i> <i>Aconitum chasmanthum</i> <i>Aconitum deinorrhizum</i> <i>Aconitum lycoctonum</i> <i>Aconitum napellus</i> <i>Aconitum spicatum</i> <i>Aconitum stoerkianum</i> <i>Aconitum uncinatum</i> <i>var. japonicum</i> | Aconite | Root | 1:10 | 1.3% of dried root, i.e. a 1:10 tincture can make up no more than 13% of the product |
| <i>Conium maculatum</i> | Hemlock | Leaf and sometimes root (leaf is preferred) | | 7% |
| <i>Pilocarpus jaborandi</i> <i>Pilocarpus microphyllus</i> | Jaborandi | Leaflets | | 5% |
| <i>Rhus toxicodendron</i> <i>Toxicodendron pubescens</i> | Poison oak | Leaf | | 10% |
| <i>Senecio jacobaea</i> <i>Jacobaea vulgaris</i> | Ragwort | Aerial parts | 1:5 | 10% of dried herb, i.e. a 1:5 tincture can make up no more than 50% of the product |



Part 1 of Schedule 20: Herbs forbidden for use

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Provision 241 of the Human Medicines Regulation 2012 also specifies that the following herbs appearing in Part 1 of Schedule 20 may only be supplied on the prescription of a registered **medical** practitioner

| Botanical source | Common name | Botanical source | Common name |
|---|-------------------|--|--|
| <i>Apocynum cannabinum</i> | Canadian hemp | <i>Holarrhena antidysenterica</i> | Holarrhena |
| <i>Areca catechu</i> | Areca | <i>Juniperus sabina</i> | Savin |
| <i>Artemisia cina</i> | Santonica | <i>Mallotus philippinensis</i> | Kamala |
| <i>Brayera anthelmintica</i> | Kousso | <i>Pausinystalia yohimbe</i> | Yohimbe bark |
| <i>Catha edulis</i> | Catha | <i>Punica granatum</i> | Pomegranate bark |
| <i>Chenopodium ambrosioides</i> <i>var. anthelminticum</i> | Chenopodium | <i>Rhus radicans</i> | Poison ivy |
| <i>Crotalaria berberoana</i> | Crotalaria fulva | <i>Scopolia carniolica</i> <i>Scopolia japonica</i> | Scopolia |
| <i>Crotalaria spectabilis</i> | Crotalaria spect. | <i>Strophanthus courmonti</i> <i>Strophanthus emini</i> <i>Strophanthus gratus</i> <i>Strophanthus hispidus</i> <i>Strophanthus kombe</i> <i>Strophanthus nicholsoni</i> <i>Strophanthus sarmentosus</i> | Strophanthus |
| <i>Cucurbita maxima</i> | Cucurbita | <i>Ulmus fulva</i> <i>Ulmus rubra</i> | Slippery elm bark (whole or unpowdered) There is no restriction on the use of powdered <i>Ulmus fulva</i> or <i>Ulmus rubra</i> |
| <i>Delphinium staphisagria</i> | Stavesacre seeds | <i>Viscum album</i> | Mistletoe berry There is no restriction on the use of other parts |
| <i>Dryopteris filix-mas</i> | Male fern | | |
| <i>Duboisia leichardtii</i> <i>Duboisia myoporoides</i> | Duboisia | | |
| <i>Ecballium elaterium</i> | Elaterium | | |
| <i>Embelia ribes</i> <i>Embelia robusta</i> | Embelia | | |
| <i>Erysimum canescens</i> | Erysimum | | |