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EMA/HMPC/572974/2014
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Ricinus communis* L., oleum

Draft

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| Rediscussion in MLWP | |
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| Keywords | Herbal medicinal products; HMPC; European Union herbal monographs; well established medicinal use; <i>Ricinus communis</i> L., oleum; Ricini oleum, Castor oil |
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| BG (bulgarski): Рициново масло CS (čeština): ricinový olej DA (dansk): Ricinusolie DE (Deutsch): Natives Rizinusöl EL (elliniká): Έλαιο κρότωνος (κικινέλαιο - ρετσινόλαδο) EN (English): Castor oil ES (español): Aceite de ricino ET (eesti keel): riitsinusõli FI (suomi): risiiniöljy FR (français): Ricin (huile de) HR (hrvatski): ricinusovo ulje HU (magyar): Ricinusolaj IT (italiano): Ricino olio | LT (lietuvių kalba): Ricinų aliejus LV (latviešu valoda): Rīcinēļļa MT (Malti): żejt ir-Riġnu NL (Nederlands): Wonderolie, ricinusolie PL (polski): olej rycynowy PT (português): Óleo-de-ricino RO (română): ulei de ricin SK (slovenčina): Ricínový olej SL (slovenščina): ricinusovo olje SV (svenska): Ricinolja <i>IS (íslenska):</i> <i>NO (norsk): Ricinusolje</i> |
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European Union herbal monograph on *Ricini communis* L., oleum

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition^{1,2}

| Well-established use | Traditional use |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| With regard to the marketing authorisation application of Article 10a of Directive 2001/83/EC as amended <i>Ricinus communis</i> L., oleum (castor oil) i) Herbal substance Not applicable. ii) Herbal preparation Fatty oil obtained from seeds of <i>Ricinus communis</i> L. by cold expression | |

3. Pharmaceutical form

| Well-established use | Traditional use |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| Herbal preparations in liquid or solid dosage forms for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term. | |

4. Clinical particulars

4.1. Therapeutic indications

| Well-established use | Traditional use |
|------------------------------------------------------------------|-----------------|
| Laxative for short term use in cases of occasional constipation. | . |

¹ The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

² The material complies with the Ph. Eur. monograph (*Ricini oleum virginale* (ref.: 0051) or *Ricini oleum raffinatum* (ref.: 2367))

4.2. Posology and method of administration

| Well-established use | Traditional use |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| <p>Posology</p> <p><i>Adults and elderly</i></p> <p>Daily dose: 2-5 g (2.1-5.3 ml) as a single dose</p> <p>Normally it is sufficient to take this medicinal product up to 2-3 times a week.</p> <p>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'special warnings and precautions for use').</p> <p>Duration of use</p> <p>Use for more than 1 week requires medical supervision.</p> <p>If the symptoms persist during the use of the medicinal product, a doctor or a pharmacist should be consulted.</p> <p>Method of administration</p> <p>Oral use</p> <p>The onset time of defecation varies between 2-6 hours.</p> | |

4.3. Contraindications

| Well-established use | Traditional use |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| <p>Hypersensitivity to the active substance.</p> <p>Cases of intestinal obstructions and stenosis, atony, appendicitis, inflammatory colon diseases (e.g. Crohn's disease, ulcerative colitis), abdominal pain of unknown origin, severe dehydration state with water and electrolyte depletion.</p> <p>Pregnancy and lactation (See section 5.3)</p> | |

4.4. Special warnings and precautions for use

| Well-established use | Traditional use |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| <p>Long-term use of laxatives should be avoided. If laxatives are needed every day the cause of constipation should be investigated.</p> <p>If stimulant laxatives are taken for longer than a brief period, this may lead to impaired function of the intestine. Castor oil should only be used if a therapeutic effect cannot be achieved by a change of diet or the administration of bulk forming agents.</p> <p>The use in children and adolescents under 18 years of age has not been established due to lack of adequate data on safety and efficacy.</p> <p>If the symptoms worsen during the use of the medicinal product, a doctor or a pharmacist should be consulted.</p> | |

4.5. Interactions with other medicinal products and other forms of interaction

| Well-established use | Traditional use |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| <p>Hypokalaemia (resulting from long-term laxative abuse) potentiates the action of cardiac glycosides and interacts with antiarrhythmic medicinal products.</p> <p>Concomitant use with diuretics, adrenal corticosteroids and liquorice root may enhance loss of potassium.</p> <p>Concomitant use of antihistamines may reduce the laxative action of castor oil.</p> | |

4.6. Fertility, pregnancy and lactation

| Well-established use | Traditional use |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| <p>The use during pregnancy is contraindicated because castor oil can influence the labour (see 5.3).</p> <p>The use during lactation is contraindicated because may pass into breast milk (see section 4.3 'Contraindication").</p> | |

| Well-established use | Traditional use |
|------------------------------|-----------------|
| No fertility data available. | |

4.7. Effects on ability to drive and use machines

| Well-established use | Traditional use |
|----------------------------------------------------------------------------------------|-----------------|
| No studies on the effect on the ability to drive and use machines have been performed. | |

4.8. Undesirable effects

| Well-established use | Traditional use |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| <p>Nausea, vomiting, abdominal pain and severe diarrhoea may occur. The frequency is not known. In such cases dose reduction is necessary.</p> <p>If other adverse reactions not mentioned above occur, a doctor or a pharmacist should be consulted.</p> | |

4.9. Overdose

| Well-established use | Traditional use |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| <p>The major symptoms of overdose are gastric irritation with nausea, vomiting, colic and severe diarrhoea, loss of water and electrolytes. Treatment should be supportive with generous amount of fluid and correction of electrolytes. A specific antidote is not available.</p> | |

5. Pharmacological properties

5.1. Pharmacodynamic properties

| Well-established use | Traditional use |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| <p>Pharmacotherapeutic group: contact laxatives</p> <p>Proposed ATC code: A 06 AB05</p> <p>Ricinoleic acid, the active metabolite, like other anionic surfactants, reduces net absorption of fluid and electrolytes, and stimulates intestinal peristalsis.</p> | |

5.2. Pharmacokinetic properties

| Well-established use | Traditional use |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| <p>The absorption is inversely related to the administered dose. Small doses of castor oil (4 g) are completely absorbed while 11.4% of a dose of 10 g and 86% of a dose of 44.4 g appeared in the faeces within 24 hours.</p> <p>The castor oil is hydrolysed in the small intestine by pancreatic enzymes, leading to the release of glycerol and ricinoleic acid.</p> <p>Ricinoleic acid is then metabolised to epoxydicarboxylic acids (3.6-epoxyoctanedioic acid, 3.6-epoxydecanedioic acid and 3.6-epoxydodecanedioic acid) which are excreted via urine.</p> | |

5.3. Preclinical safety data

| Well-established use | Traditional use |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| <p>Castor oil (2 ml/daily) administered by gavage on days 18, 19 and 20 of gestation induced the initiation of labour and shortened the course of the delivery in pregnant rats.</p> <p>Adequate tests on genotoxicity and carcinogenicity have not been performed.</p> | |

6. Pharmaceutical particulars

| Well-established use | Traditional use |
|----------------------|-----------------|
| Not applicable. | |

7. Date of compilation/last revision

7 July 2015