Health Canada Santé Canada

PRODUIT DE SANTÉ NATUREL

EXTRAITS ET ISOLATS DE FÈVES DE SOJA

La présente monographie vise à servir de guide à l'industrie pour la préparation de demandes de licence de mise en marché (DLMM) et d'étiquettes dans le but d'obtenir une autorisation de mise en marché d'un produit de santé naturel. Elle ne vise pas à être une étude approfondie de l'ingrédient médicinal.

Nota

- Les parenthèses contiennent des éléments d'information additionnels (facultatifs) qui peuvent être inclus dans la DLMM ou sur l'étiquette du produit à la discrétion du demandeur.
- La barre oblique (/) indique que les termes et/ou énoncés sont synonymes. Le demandeur peut utiliser n'importe lequel des termes ou énoncés indiqués.

Date 1 juillet 2019

Nom(s) propre(s), Nom(s) commun(s), Matière(s) d'origine

Tableau 1. Nom(s) propre(s), Nom(s) commun(s), Matière(s) d'origine

Nom(s) propre(s)	Nom(s) commun(s)	Matière(s) d'origine - ingrédient(s)	Matière(s) d'origine		Préparation(s)
		Nom(s) commun(s)	Nom(s) propre(s)	Partie(s)	
▶ 4',5,7-Trihydroxyisoflavone ▶ 5,7-Dihydroxy-3-(4-hydroxyphényl)-4H-1-benzopyran-4-one	Génistéine	▶ Extrait d'isoflavone de soja ▶ Extrait de protéine de soja ▶ Génistéine ▶ Isolat de protéine de soja	*Glycine max*	Graine	Isolat
7-(bêta-D-glucopyranosyloxy)-3-(4-hydroxyphényl)-4H-1-Benzopyran-4-one	▶ 7-O-bêta-D-Glucopyranoside ▶ Génistine ▶ Génistine 7-glucoside	▶ Extrait d'isoflavone de soja ▶ Extrait de protéine de soja ▶ Génistine ▶ Isolat de protéine de soja	*Glycine max*	Graine	Isolat
Glycine max	▶ Da dou ▶ Fève de soja ▶ Fève soja ▶ Soja ▶ Soja noir	S/O	*Glycine max*	Graine	S/O

Extrait d'isoflavone de soja	Extrait d'isoflavone de soja	S/O	*Glycine max*	Graine	S/O
Extrait de protéine de soja	Extrait de protéine de soja	S/O	*Glycine max*	Graine	S/O
Isolat de protéine de soja	Isolat de protéine de soja	S/O	*Glycine max*	Graine	S/O

Références: Noms propres: BDIPSN 2019, USDA 2019, Evans et al. 2007, Newton et al. 2006, Roudsari et al. 2005, Arjamandi et al. 2003, Yamori et al. 2002, Alekel et al. 2000, Scambia et al. 2000, Upmalis et al. 2000 Wangen et al. 2000, Potter et al. 1998; Noms communs: BDIPSN 2019, Evans et al. 2007, Newton et al. 2006, Roudsari et al. 2005, Arjamandi et al. 2003, Yamori et al. 2002, Alekel et al. 2000, Wangen et al. 2000, Potter et al. 1998; Matières d'origine: BDIPSN 2019, USDA 2019, D'Anna et al. 2007, Evans et al. 2007, Nahas et al. 2007, Newton et al. 2006, Ye et al. 2006, Roudsari et al. 2005, Crisafulli et al. 2004, Harkness et al. 2004, Kreijkamp-Kaspers et al. 2004, Arjamandi et al. 2003, Uesugi et al. 2003, Han et al. 2002, Albert et al. 2002, Faure et al. 2002, Yamori et al. 2002, Alekel et al. 2000, Wangen et al. 2000, Albertazzi et al. 1998, Potter et al. 1998.

Voie d'administration

Orale

Forme(s) posologique(s)

Cette monographie exclut les aliments et les formes posologiques semblables aux aliments tel qu'indiqué dans le document de référence Compendium des monographies.

Les formes posologiques acceptables pour les catégories d'âge listées dans cette monographie et pour la voie d'administration spécifiée sont indiquées dans le document de référence Compendium des monographies.

Usage(s) ou fin(s)

- Lorsque combiné à un apport suffisant de calcium et de vitamine D, aide à réduire/atténuer la perte de la densité minérale osseuse (DMO) chez les femmes en post-ménopause (Marini et al. 2007; Newton et al. 2006; Ye et al. 2006; Chen et al. 2004; Kreijkamp-Kaspers et al. 2004; Lydeking et al. 2004; Uesugi et al. 2003; Alekel et al. 2000; Potter et al. 1998).
- Pourrait réduire les symptômes graves et fréquents liés à la ménopause (tels que les bouffées de chaleur et/ou les sueurs nocturnes) (D'Anna et al. 2007; Nahas et al. 2007; Williamson- Hughes et al. 2006; Crisafulli et al. 2004; Albert et al. 2002; Han et al. 2002; Scambia et al. 2000; Upmalis et al. 2000; Albertazzi et al. 1998).

L'(Les) usage(s) combiné(s) suivant(s) est/sont aussi acceptable(s):

Pourrait réduire les symptômes graves et fréquents liés à la ménopause (tels que les bouffées de chaleur et/ou les sueurs nocturnes) et aider à réduire/atténuer la perte de la densité minérale osseuse (DMO) chez les femmes en post-ménopause lorsque combiné à un apport suffisant de calcium et de

vitamine D (D'Anna et al. 2007; Marini et al. 2007; Nahas et al. 2007; Newton et al. 2006; Williamson-Hughes et al. 2006; Ye et al. 2006; Chen et al. 2004; Crisafulli et al. 2004; Kreijkamp-Kaspers et al. 2004; Lydeking et al. 2004; Uesugi et al. 2003; Albert et al. 2002; Han et al. 2002; Alekel et al. 2000; Scambia et al. 2000; Upmalis et al. 2000; Albertazzi et al. 1998; Potter et al. 1998).

Dose(s)

Sous-population(s)

Femmes ménopausées et en post-ménopause (D'Anna et al. 2007; Nahas et al. 2007; Crisafulli et al. 2004; Albert et al. 2002; Faure et al. 2002; Han et al. 2002; Scambia et al. 2000; Upmalis et al. 2000; Albertazzi et al. 1998).

Quantité(s)

Réduction de la perte de la DMO

Glycine max, Extrait d'isoflavone de soja, Extrait de protéine de soja, Isolat de protéine de soja

Méthodes de préparation : Extraits normalisés

75 à 125 milligrammes d'Équivalents Aglycones d'Isoflavones (ÉAI) totaux, par jour; ne pas dépasser 35 grammes d'extrait/d'isolat de protéine de soja, par jour (FCÉN 2015; Marini et al. 2007; Newton et al. 2006; Ye et al. 2006; Chen et al. 2004; CPS 2004; Kreijkamp-Kaspers et al. 2004; Lydeking et al. 2004; Uesugi et al. 2003; Alekel et al. 2000; Potter et al. 1998).

Génistéine, Génistine

Méthodes de préparation : Isolats

75 à 125 milligrammes d'Équivalents Aglycones d'Isoflavones (ÉAI) totaux, par jour (Marini et al. 2007; Newton et al. 2006; Ye et al. 2006; Chen et al. 2004; Kreijkamp-Kaspers et al. 2004; Lydeking et al. 2004; Uesugi et al. 2003; Alekel et al. 2000; Potter et al. 1998).

Réduction des symptômes liés à la ménopause

Glycine max, Extrait d'isoflavone de soja, Extrait de protéine de soja, Isolat de protéine de soja

Méthodes de préparation : Extraits normalisés

30 à 125 milligrammes d'ÉAI totaux, avec un minimum de 15 milligrammes d'ÉAI provenant des composés de la génistéine/génistine, par jour; ne pas dépasser 35 grammes d'extrait/d'isolat de protéine de soja, par jour (FCÉN 2015; D'Anna et al. 2007; Nahas et al. 2007; Williamson-Hughes et al. 2006; CPS 2004; Crisafulli et al. 2004; Albert et al. 2002; Han et al. 2002; Scambia et al. 2000; Upmalis et al. 2000; Albertazzi et al. 1998).

Génistéine, Génistine

Méthodes de préparation : Isolats

15 à 125 milligrammes d'ÉAI totaux, par jour (D'Anna et al. 2007; Nahas et al. 2007; Williamson-Hughes et al. 2006; Crisafulli et al. 2004; Albert et al. 2002; Han et al. 2002; Scambia et al. 2000; Upmalis et al. 2000; Albertazzi et al. 1998).

Mode(s) d'emploi

Prendre quelques heures précédant ou suivant la prise de médicaments ou de produits de santé (Sweetman 2007; ASHP 2005).

Durée(s) d'utilisation

Réduction de la perte de la DMO

Utiliser pendant au moins 6 mois afin de pouvoir constater les effets bénéfiques (Ye et al. 2006; Harkness et al. 2004; Alekel et al. 2000; Potter et al. 1998).

Réduction des symptômes liés à la ménopause

Utiliser pendant au moins 2 semaines afin de pouvoir constater les effets bénéfiques (D'Anna et al. 2007; Nahas et al. 2007; Crisafulli et al. 2004; Han et al. 2002; Scambia et al. 2000; Upmalis et al. 2000; Albertazzi et al. 1998).

Tous les usages

Consulter un praticien de soins de santé/fournisseur de soins de santé/professionnel de la santé/ docteur/médecin si l'usage se prolonge au-delà d'1 an (Tomar et Shiao 2008; BfR 2007; Duffy et al. 2007; Palacios et al. 2007; Unfer et al. 2004; Petrakis et al. 1996).

Mention(s) de risque

Précaution(s) et mise(s) en garde

Tous les produits

- Avant d'en faire l'usage, assurez-vous que votre dossier médical est à jour quant aux mammographies et aux évaluations gynécologiques (Tomar et Shiao 2008; BfR 2007; Duffy et al. 2007; Palacios et al. 2007; Unfer et al. 2004; Petrakis et al. 1996).
- Consulter un praticien de soins de santé/fournisseur de soins de santé/professionnel de la santé/docteur/médecin si les symptômes s'aggravent.

- Consulter un praticien de soins de santé/fournisseur de soins de santé/professionnel de la santé/docteur/médecin avant d'en faire l'usage si vous prenez des anticoagulants ou si vous suivez un traitement hormonal substitutif, y compris une hormonothérapie thyroïdienne substitutive (Rios et al. 2008; BfR 2007; Messina and Redmond 2006; ASHP 2005; Izzo et al. 2005; Mills and Bone 2005; Franco et al. 2004; Mazer 2004; Murray et al. 2003; Cambria-Keily 2002; Bell and Ovalle 2001; IOM 2001; Hansten et al. 1997; Petrakis et al. 1996).
- Consulter un praticien de soins de santé/fournisseur de soins de santé/professionnel de la santé/docteur/médecin avant d'en faire l'usage si vous souffrez de maladies du foie, si vous développez des symptômes liés à des troubles du foie (par ex. de la douleur abdominale, de la jaunisse, de l'urine foncée) ou si vous avez des antécédents de maladies hormonales ou gynécologiques, y compris le cancer de l'ovaire, l'endométriose, et/ou les fibromes utérins (Cecchi et al. 2009; NIH 2009; Chandrareddy et al. 2008; Gasteyger et al. 2008; Tomar and Shiao 2008; Jefferson et al. 2007; Palacios et al. 2007; Kaari et al. 2006; Noel et al. 2006; Maskarinec et al. 2004a; Maskarinec et al. 2004b; Unfer et al. 2004; Borghi-Scoazec et al. 2002; Wu et al. 2000; Duncan et al. 1999b; Hargreaves et al. 1999; McMichael-Phillips et al. 1998; Petrakis et al. 1996).
- Cesser l'utilisation et consulter un praticien de soins de santé/fournisseur de soins de santé/ professionnel de la santé/docteur/médecin si vous ressentez des douleurs, une gêne ou un endolorissement mammaires, si vous avez une récurrence des menstruations, ou si vous avez de petits saignements utérins (spotting) (Chandrareddy et al. 2008; Martinez and Lewi 2008; Palacios et al. 2007; Olawaiye et al. 2005; Albert et al. 2002; Han et al. 2002; Hargreaves etal. 1999; McMichael-Phillips et al. 1998; Petrakis et al. 1996).

Contre-indication(s)

Ne pas utiliser ce produit si vous souffrez ou avez déjà souffert de cancer du sein, si vous avez ou avez déjà eu des tumeurs du sein, si vous avez des prédispositions au cancer du sein, telles qu'indiquées par une mammographie et/ou une biopsie anormale, ou si vous avez des antécédents familiaux de cancer du sein (Helferich et al. 2008; Tomar et Shiao 2008; BfR 2007; Duffy et al. 2007; Kaari et al. 2006; Nikander et al. 2005; Hargreaves et al. 1999; McMichael- Phillips et al. 1998; Petrakis et al. 1996).

Réaction(s) indésirable(s) connue(s)

Énoncé non requis.

Ingrédients non médicinaux

Doivent être choisis parmi ceux de la version actuelle de la Base de données des ingrédients des produits de santé naturels (BDIPSN) et respecter les restrictions mentionnées dans cette base de données.

Conditions d'entreposage

Énoncé non requis.

Spécifications

- Les spécifications du produit fini doivent être établies conformément aux exigences décrites dans le Guide de référence sur la qualité des produits de santé naturels de la Direction des produits de santé naturels et sans ordonnance (DPSNSO).
- L'ingrédient médicinal doit être conforme aux exigences mentionnées dans la BDIPSN.
- Suivre les méthodes énoncées dans « AOAC 2008.03 » afin d'effectuer des mesures précises des isoflavones exprimées en ÉAI (Collison 2008).

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Annexe 1 : Définitions et facteurs de conversion

Définitions :

Équivalents aglycones d'isoflavones (ÉAI) : la quantité maximale d'isoflavones biodisponibles suite à leur ingestion. Afin que les isoflavones puissent être absorbés par l'organisme, les liens glycosidiques des isoflavones sous forme de glycosides doivent être clivés pour produire les formes aglycones correspondantes. Si les quantités d'isoflavones sous forme de glycosides et aglycones sont additionnées sans tenir compte de la transformation biochimique des composés, la quantité biodisponible sera surestimée par un facteur de deux (Wang et Murphy 1996).

Facteurs de conversion :

La quantité d'isoflavones doit toujours être calculée et exprimée en ÉAI (c.-à-d. en fonction de la génistéine, la daidzéine et/ou la glycitéine), et ce, pour toutes les formes d'isoflavones retrouvées dans le produit i.e. les glycosides, leurs composés acétyl et malonyl et/ou les formes aglycones.

Tableau 2: Conversion de la quantité des isoflavones en équivalent d'isoflavones aglycones (ÉAI) (Collison 2008)

Isoflavone (1 mg)	Equivalent d'isoflavones aglycones (mg ÉAI)
Génistéine	1,0
Génistine	0,625
Génistine, son composé malonyl	0,521
Génistine, son compose acétyl	0,570
Daidzéine	1,0
Daidzine	0,611
Daidzine, son composé malonyl	0,506
Daidzine, son composé acétyl	0,555
Glycitéine	1,0
Glycitine	0,637
Glycitine, son composé malonyl	0,534
Glycitine, son composé acétyl	0,582

Exemple d'utilisation des facteurs de conversion ÉAI :

Convertir la quantité de glycosides en ÉAI (mg) :

Convertir 20 mg de génistine en mg ÉAI :
= 20 mg x 0,625 mg ÉAI/mg génistine
= 12,5 mg ÉAI génistine

Annexe 2 : Comment calculer et présenter les quantités totales d'isoflavones sur le formulaire de DLMM

1) Exemple d'un produit à base d'extrait de protéine de soja, à une dose de 30 g, par jour :

Pour un produit ayant une allégation liée à la réduction des symptômes de la ménopause, la quantité totale de protéine, des composés d'isoflavones, et de génistéine/génistine doit être indiqué sur le formulaire de DLMM :

a) Calculer la quantité totale d'isoflavones (mg ÉAI)

Convertir la quantité ÉAI de génistine et ses composés malonyl et acétyl, de génistéine, de daidzéine et de daidzine en quantités ÉAI (mg) totales d'isoflavones :
=1,5 mg ÉAI (génistine) + 10 mg ÉAI (génistéine) + 1 mg ÉAI (génistine, son composé malonyl) + 1 mg ÉAI (génistine, son composé acétyl) + 6,1 mg ÉAI (daidzine) + 5 mg ÉAI (daidzéine)
=35,6 mg ÉAI (quantité totale d'isoflavones)

b) Calculer la quantité des composés de génistéine/génistine (mg ÉAI)

Convertir la quantité ÉAI de génistine et ses composés malonyl et acétyl et de génistéine en quantités ÉAI (mg) totales d'isoflavones :
=12,5 mg ÉAI (génistine) + 10 mg ÉAI (génistéine) + 1 mg ÉAI (génistine, son composé malonyl) + 1 mg ÉAI (génistine, son composé acétyl)
=24,5 mg ÉAI (composés de génistéine/génistine)

c) Présenter les données sur le formulaire de DLMM de la façon suivante :

Nom propre de l'ingrédient médicinal : Extrait de protéine de soja
Nom commun de l'ingrédient médicinal : Extrait de protéine de soja
Quantité de l'ingrédient médicinal : 30 g
Matière d'origine : *Glycine max* - graine
Activités :
Quantité totale d'isoflavones: 35,6 mg ÉAI
Génistéine/génistine : 24,5 mg ÉAI

2) Exemple d'un produit à base d'isolat de génistéine/génistine, à une dose de 30 mg, par jour:

Pour un produit ayant une allégation liée à la réduction des symptômes de la ménopause, la quantité totale de génistéine/génistine doit être indiquée sur le formulaire de DLMM.

Présenter les données sur le formulaire de DLMM de la façon suivante :

Nom propre de l’ingrédient médicinal : Génistéine/génistine
Nom commun de l’ingrédient médicinal : Génistéine/génistine
Quantité de l’ingrédient médicinal : 30 mg ÉAI
Matière d’origine - ingrédient : Extrait d'isoflavone de soja ou Extrait de protéine de soja ou Isolat de protéine de soja ou Aucune
Matière d’origine : *Glycine max* - graine
Activités : Aucune