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.

Notes

- Les parenthèses contiennent des éléments d'information additionnels (facultatifs) qui peuvent être inclus sur l'étiquette 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 sur l'étiquette.

Date 27 septembre 2024

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

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

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

Nom(s) propre(s)	Nom(s) commun(s)	Information(s) d'origine		
		Matière(s) d'origine -ingrédient(s)	Matière(s) d'origine	Partie(s)
Isolat de protéines de soja[1]	Isolat de protéines de soja	S/O	*Glycine max*	Graine

Références: Noms propres: BDIPSN 2024, USDA 2024, 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 2024, 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; Informations d'origine: BDIPSN 2024, USDA 2024, 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.

[1]Pour les isolats, l'information d'activité doit être équivalente à 90% ou plus de protéines en 'poids sec'.

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 la voie d'administration orale sont indiquées dans la liste déroulante dans le formulaire web de demande de licence de mise en marché pour les demandes officinales.

Usage(s) ou fin(s)

- Aide à réduire/atténuer/diminuer la perte (de la densité minérale) osseuse (DMO) chez les femmes en postménopause, lorsque combiné à un apport suffisant de calcium et de vitamine D (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).

Dose(s)

Sous-population(s)

Femmes en périménopause; Femmes en postménopause (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

Méthodes de préparation : Extraits normalisés

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).

Concentré de protéines de soja, Isolat de protéines de soja

75 à 125 milligrammes d'ÉAI totaux, par jour; Ne pas dépasser 35 grammes de concentré/d'isolat de protéines de soja, par jour (FCÉN 2024; 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

75 à 125 milligrammes d'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

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 (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).

Concentré de protéines de soja, Isolat de protéines de soja

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 de concentré/d'isolat de

protéines de soja, par jour (FCÉN 2024; 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

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 avant ou après la prise d'autres médicaments ou 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'utilisation 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

- **Consultez un praticien de soins de santé/fournisseur de soins de santé/professionnel de la santé/docteur/médecin avant l'utilisation si** vous n'êtes pas à jour dans les mammographies et évaluations gynécologiques (Tomar et Shiao 2008; BfR 2007; Duffy et al. 2007; Palacios et al. 2007; Unfer et al. 2004; Petrakis et al. 1996).
- **Consultez un praticien de soins de santé/fournisseur de soins de santé/professionnel de la santé/docteur/médecin si** les symptômes s'aggravent.

- **Consultez un praticien de soins de santé/fournisseur de soins de santé/professionnel de la santé/docteur/médecin avant l'utilisation si** vous prenez des anticoagulants ou tout traitement hormonal substitutif (Rios et al. 2008; BfR 2007; Messina et Redmond 2006; ASHP 2005; Izzo et al. 2005; Mills et Bone 2005; Franco et al. 2004; Mazer 2004; Murray et al. 2003; Cambria-Keily 2002; Bell et Ovalle 2001; IOM 2001; Hansten et al. 1997; Petrakis et al. 1996).
- **Consultez un praticien de soins de santé/fournisseur de soins de santé/professionnel de la santé/docteur/médecin avant l'utilisation si** vous avez une maladie du foie ou des antécédents de maladies hormonales ou gynécologiques (NIH 2022; Cecchi et al. 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).

Contre-indication(s)

Ne pas utiliser si vous avez ou avez déjà eu un cancer ou des tumeurs du sein, des prédispositions au cancer du sein, telles qu'indiquées par une mammographie ou une biopsie anormale, ou 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)

Cessez d'utiliser et consultez un praticien de soins de santé/fournisseur de soins de santé/ professionnel de la santé/docteur/médecin si vous développez de nouveaux symptômes tels qu'une douleur mammaire, une récurrence de menstruations, de petits saignements utérins (spotting) ou des symptômes liés à des troubles du foie (par ex., de la douleur abdominale, de la jaunisse, de l'urine foncée) (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).

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

Doivent être établies conformément aux exigences décrites dans le *Règlement sur les produits de santé naturels*.

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).

EXEMPLE D'INFO-PRODUIT :

Veuillez consulter la ligne directrice, Étiquetage des produits de santé naturels pour plus de détails.

Info-Produit
Ingrédient médicinal dans chaque capsule *Glycine max (Soja) – extrait de graine* XX mg Fournissant XX mg d'Équivalents Aglycones d'Isoflavones (ÉAI) totaux Incluant XX mg d'ÉAI de génistéine et/ou XX mg d'ÉAI de génistine
Usages • Aide à réduire la perte de la densité minérale osseuse (DMO) chez les femmes en postménopause, lorsque combiné à un apport suffisant de calcium et de vitamine D. • Pourrait réduire les symptômes graves et fréquents liés à la ménopause tels que les bouffées de chaleur et/ou les sueurs nocturnes.
Mises en garde
Allergène: Soja
Si applicable[1] : **Allergènes: autres allergène alimentaire, gluten (source de gluten), sulfites** **Contient de l'aspartame**
Ne pas utiliser si vous avez ou avez déjà eu un cancer ou des tumeurs du sein, des prédispositions au cancer du sein, telles qu'indiquées par une mammographie ou une biopsie anormale, ou des antécédents familiaux de cancer du sein.
Consultez un praticien de soins de santé avant l'utilisation si • vous n'êtes pas à jour dans les mammographies et évaluations gynécologiques • vous prenez des anticoagulants ou tout traitement hormonal substitutif • vous avez une maladie du foie ou des antécédents de maladies hormonales ou gynécologiques.
Cessez d'utiliser et consultez un praticien de soins de santé si vous développez de nouveaux symptômes tels qu'une douleur mammaire, une récurrence de menstruations, de petits saignements utérins (spotting) ou des symptômes liés à des troubles du foie (par ex., de la douleur abdominale, de la jaunisse, de l'urine foncée).
Consultez un praticien de soins de santé si les symptômes s'aggravent.
Mode d'emploi Femmes en périménopause et en postménopause : • Prendre X capsule(s), X fois par jour • Prendre quelques heures avant ou après la prise d'autres médicaments ou produits de santé • Consulter un praticien de soins de santé si l'utilisation se prolonge au-delà d'1 an • Utiliser pendant au moins 6 mois afin de pouvoir constater les effets bénéfiques (pour la perte de la DMO) • Utiliser pendant au moins 2 semaines afin de pouvoir constater les effets bénéfiques (pour les symptômes liés à la ménopause)[2].
Autres renseignements (Ajoutez les informations d'entreposage)
Ingrédients non-médicinaux Énumérez tous les INM
Questions? (Appelez) 1-XXX-XXX-XXXX

[1]Cette section peut être retirée du tableau si le produit ne contient pas d'allergène ou d'aspartame.
[2]Les qualificatifs (pour la perte de la DMO) et (pour les symptômes liés à la ménopause) devraient être ajoutés sur l'étiquette si les deux usages sont listés sur l'étiquette pour informer les consommateurs.

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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)	Équivalent d'isoflavones aglycones (mg d'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 d'ÉAI : Convertir la quantité de glycosides en ÉAI (mg) : Convertir 20 mg de génistine en mg d'ÉAI :
= 20 mg x 0,625 mg d'ÉAI/mg génistine
= 12,5 mg d'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 de concentré de protéines 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 protéines, des composés d'isoflavones, et de génistéine/génistine doit être indiqué sur le formulaire de DLMM :

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

Convertir la quantité d'ÉAI de génistine et ses composés malonyl et acétyl, de génistéine, de daidzéine et de daidzine en quantités d'ÉAI (mg) totales d'isoflavones :

=1,5 mg d'ÉAI (génistine) + 10 mg d'ÉAI (génistéine) + 1 mg d'ÉAI (génistine, son composé malonyl) + 1 mg d'ÉAI (génistine, son composé acétyl) + 6,1 mg d'ÉAI (daidzine) + 5 mg d'ÉAI (daidzéine)
=35,6 mg d'ÉAI (quantité totale d'isoflavones)

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

Convertir la quantité d'ÉAI de génistine et ses composés malonyl et acétyl et de génistéine en quantités d'ÉAI (mg) totales d'isoflavones :

=12,5 mg d'ÉAI (génistine) + 10 mg d'ÉAI (génistéine) + 1 mg d'ÉAI (génistine, son composé malonyl) + 1 mg ÉAI (génistine, son composé acétyl)
=24,5 mg d'ÉAI (composés de génistéine/génistine)

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

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

Matière d'origine - ingrédient : Génistéine/génistine
Matière d'origine : *Glycine max* - graine
Activités : Aucune