

PRODUIT DE SANTÉ NATUREL

COENZYME Q₁₀ (UBIQUINONE-10)

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 les énoncés sont synonymes. Le demandeur peut utiliser n'importe lequel des termes ou énoncés indiqués.

Date

31 juillet 2018

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

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

Nom(s) propre(s)	Nom(s) commun(s)	Matière(s) d'origine			
		Nom(s) propre(s)	Nom(s) commun(s)	Partie(s)	Préparation(s)
2,5-Cyclohexadiène-1,4-dione, 2-[(2E,6E,10E,14E,18E,22E,26E,30E,34E)-3,7,11,15,19,23,27,31,35,39-décaméthyl-2,6,10,14,18,22,26,30,34,38-tétracontadécaényl]-5,6-diméthoxy-3-méthyl	<ul style="list-style-type: none"> ▶ Coenzyme Q₁₀, ▶ CoQ₁₀ ▶ Ubidécarénone ▶ Ubiquinone-10 	<ul style="list-style-type: none"> ▶ <i>Agrobacterium rhizogenes</i> ▶ <i>Agrobacterium tumefaciens</i> ▶ <i>Aspergillus clavatus</i> ▶ <i>Escherichia coli</i> ▶ <i>Escherichia coli</i> ▶ <i>Gluconobacter suboxydans</i> ▶ <i>Leucosporidium scotti</i> ▶ <i>Paracoccus denitrificans</i> ▶ <i>Rhodobacter sphaeroides</i> ▶ <i>Rhodospirillum rubrum</i> ▶ <i>Saccharomyces cerevisiae</i> ▶ <i>Schizosaccharomyces pombe</i> 	N/A	Cellule entière	Biosynthèse
		N/A	Coenzyme Q10		

Références: Nom propre: USP30 2006; Noms communs: Storch et al. 2007, Sweetman 2007, USP30 2006, Park et al. 2005, O'Neil et al. 2001; Matières d'origine: Lipshutz et al. 2005, Kawamukai 2002, Lipshutz et al. 2002, Szkopinska 2000, Yoshida et al. 1998, Zhao et al.1997.

Voie d'administration

Orale

Forme(s) posologiques(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)

- ▶ Aide au maintien et/ou au soutien de la santé cardiovasculaire (Rosenfeldt et al. 2007; Baggio et al. 1994; Langsjoen et al. 1988).
- ▶ Aide à réduire la fréquence des migraines ainsi que les nausées et vomissements qui les accompagnent lorsqu'elle est prise à titre prophylactique/préventif (Hershey et al. 2007; Sandor et al. 2005; Rozen et al. 2002).
- ▶ (Fournit) Un antioxydant (Kalpravidh et al. 2005; Rosenfeldt et al. 2005; Crane 2001; Chello et al. 1994).

Dose(s)

Sous-population(s)

Adultes 18 ans et plus

Quantité(s)

Antioxydant

Ne pas dépasser 300 milligrammes de Coenzyme Q₁₀, par jour (Bonakdar et Guarneri 2005; Kalpravidh et al. 2005; Rosenfeldt et al. 2005; Chello et al. 1994; Langsjoen 1994; Langsjoen et al. 1988; Tanaka et al. 1982)

Santé cardiovasculaire

30 à 300 milligrammes de Coenzyme Q₁₀, par jour (Bonakdar et Guarneri 2005; Kalpravidh et al. 2005; Rosenfeldt et al. 2005; Chello et al. 1994; Langsjoen 1994; Langsjoen et al. 1988; Tanaka et al. 1982)

Prophylaxie/prévention de la migraine

150 à 300 milligrammes de Coenzyme Q₁₀, par jour (Sandor et al. 2005; Rozen et al. 2002)

Mode(s) d'emploi

Énoncé non requis.

Durée(s) d'utilisation

Prophylaxie/prévention de la migraine

Utiliser pour au moins 3 mois afin d'observer les effets bénéfiques (Hershey et al. 2007; Sandor et al. 2005; Rozen et al. 2002).

Autres usages

Énoncé non requis.

Mention(s) de risque

Précaution(s) et mise(s) en garde

Tous les produits

- ▶ 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 êtes enceinte ou si vous allaitez.
- ▶ 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 médicaments pour la pression sanguine (Rosenfeldt et al. 2007; Singh et al. 1999).

Produits fournissant plus de 100 mg de Coenzyme Q₁₀ par jour

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 (Engelsen et al. 2003; Landbo et Almdal 1998; Spigset 1994).

Prophylaxie/prévention de la migraine

Consulter un praticien de soins de santé/fournisseur de soins de santé/professionnel de la santé/docteur/médecin si la fréquence des migraines augmente ou si les nausées et les vomissements qui les accompagnent persistent ou s'aggravent.

Contre-indication(s)

Énoncé non requis.

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.

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