

KINGDOM OF BELGIUM -----
FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS
<b>Royal Decree amending the Royal Decree of 6 September 2017 regulating narcotic and psychotropic substances</b>
PHILIPPE, King of the Belgians,
To all those present and to come, Greetings.
Having regard to Article 108 of the Constitution;
Having regard to the Law of 24 February 1921 concerning the trafficking of poisonous, soporific, narcotic, psychotropic, disinfectant or antiseptic substances and substances which may be used in the illicit manufacture of narcotic and psychotropic substances, Article 1(1), first and second subparagraphs, as inserted by the Law of 7 February 2014;
Having regard to the Royal Decree of 6 September 2017 regulating narcotic and psychotropic substances;
Having regard to the opinion of the Finance Inspectorate delivered on 17 November 2025;
Having regard to Opinion No xxxxx/x of the Council of State, delivered on ... (date), pursuant to Article 84(1), first subparagraph, point 2, of the Laws on the Council of State, consolidated on 12 January 1973;
On the proposal of the Minister for Public Health,
<b>WE HAVE DECREED AND HEREBY DECREE:</b>
<b>Article 1.</b> In Annex IA to the Royal Decree regulating narcotic and psychotropic substances, the substance listed in Annex I attached to this Decree, is inserted under the line starting with 'BUTONITAZENE'.
<b>Art. 2.</b> In Annex IIB to the same Decree, the substances listed in Annex II attached to this Decree, are inserted under the line starting with 'DIPENTYLONE'.
<b>Art. 3.</b> In Annex III to the same Decree, the substances listed in Annex III annexed to this Decree are inserted under the line starting with 'BROMAZOLAM'.
<b>Art. 4.</b> In Annex IVB to the same Decree, the following amendments are made:
1° the following lines shall be removed:

a) the line starting with 'PROTONITAZEPIPNE (N-PIPERIDINYL PROTONITAZENE)'
b) The line starting with 'METONITAZEPYNE (N-PYRROLIDINO METONITAZENE)'
c) The line starting with 'ETONITAZEPIPNE'
d) The line starting with 'N-DESETHYL ETONITAZENE'
e) The line starting with 'HEXAHYDROCANNABINOL'
2° the substances listed in Annex IV attached to this Decree, shall be inserted under the line starting with 'THCjd (TETRAHYDROCANNABIOCTYL)'
<b>Art. 5.</b> Annex IVC to the same Decree is replaced by the annex V annexed to this Decree.
<b>Art. 6.</b> Articles 4, 2° and 5 shall enter into force four months after the publication of this decree in the Belgian Official Gazette.
<b>Art. 7.</b> The Minister for Public Health shall be responsible for the implementation of this Decree.
Done at ..., on ...
By the King:
The Minister for Public Health,
Frank VANDENBROUCKE

ANNEX I: substances to be included in Annex IA

DCI <sup>1</sup> ou nom commun/vulgaire	INN <sup>2</sup> , or common/vernacular name	Nom chimique (Anglais) / Chemical name (English) of la désignation UICPA <sup>3</sup> / IUPAC designation <sup>4</sup>
N-PYRROLIDINO PROTONITAZÈNE (PROTONITAZÉPYNE)	N-PYRROLIDINO PROTONITAZÈNE (PROTONITAZÉPYNE)	5-nitro-2-(4-propoxybenzyl)-1-(2-(pyrrolidin-1-yl)ethyl)-1H-benzo[d]imidazole
N-PYRROLIDINO MÉTONITZÈNE (MÉTONITAZÉPYNE)	N-PYRROLIDINO METONITZÈNE (METONITAZÉPYNE)	2-(4-methoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1H-benzo[d]imidazole
ÉTONITAZÉ PIPNE (N-PIPÉRIDINYL ÉTONITAZÈNE)	ÉTONITAZÉ PIPNE (N-PIPÉRIDINYL ÉTONITAZÈNE)	2-[(4-Ethoxyphenyl)methyl]-5-nitro-1-(2-pyrrolidin-1-ylethyl)-1H-benzoimidazole

<sup>1</sup> Dénominations Communes Internationales

<sup>2</sup> International non-proprietary names

<sup>3</sup> Désignation chimique selon les règles de l'Union internationale de chimie pure et appliquée (UICPA), <http://www.iupac.org/>, Livre bleu, Nomenclature des composés organiques

<sup>4</sup> Chemical designation according to the rules of the International Union of Pure and Applied Chemistry (IUPAC), <http://www.iupac.org/>, Blue Book, Nomenclature of Organic Compounds

N- DESÉTHYL - ISOTONITAZ ÈNE	N-DESETHYL- ISOTONITAZE NE	N-ethyl-2-(2-(4-isopropoxybenzyl)- 5-nitro-1H-benzo[d]imidazol-1- yl)ethan-1-amine
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Examined for attachment to our Decree of ...

By the King:

The Minister for Public Health,

Frank VANDENBROUCKE

Annex II: Substance to be inserted in Annex IIB

DCI <sup>5</sup> ou nom commun/vulgaire	INN <sup>6</sup> , or common/vernacular name	Nom chimique (Anglais) / Chemical name (English) of la désignation UICPA <sup>7</sup> / IUPAC designation <sup>8</sup>
HEXAHYDROCANNABINOL	HEXAHYDROCANNABINOL	6,6,9-trimethyl-3-pentyl-6a,7,8,9,10,10a-hexahydro-6H-benzo[c]chromen-1-ol
2-FLUORODESCHLOROKÉTAMINE (2-FDCK)	2-FLUORODESCHLOROKETAMINE (2-FDCK)	2-(2-fluorophenyl)-2-(methylamino)cyclohexan-1-one

Examined for attachment to our Decree of ...

By the King:

The Minister for Public Health,

Frank VANDENBROUCKE

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<sup>5</sup> Dénominations Communes Internationales

<sup>6</sup> International non-proprietary names

<sup>7</sup> Désignation chimique selon les règles de l'Union internationale de chimie pure et appliquée (UICPA), <http://www.iupac.org/>, Livre bleu, Nomenclature des composés organiques

<sup>8</sup> Chemical designation according to the rules of the International Union of Pure and Applied Chemistry (IUPAC), <http://www.iupac.org/>, Blue Book, Nomenclature of Organic Compounds

Annex III: Substance to be inserted in Annex III

DCI <sup>9</sup> ou nom commun/vulgaire	INN <sup>10</sup> , or common/vernacular name	Nom chimique (Anglais) / Chemical name (English) of la désignation UICPA <sup>11</sup> / IUPAC designation <sup>12</sup>
CARISOPRODOL	CARISOPRODOL	2-[(carbamoyloxy)methyl]-2-methylpentyl(1-ethylethyl)carbamate

Examined for attachment to our Decree of ...

By the King:

The Minister for Public Health,

Frank VANDENBROUCKE

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<sup>9</sup> Dénominations Communes Internationales

<sup>10</sup> International non-proprietary names

<sup>11</sup> Désignation chimique selon les règles de l'Union internationale de chimie pure et appliquée (UICPA), <http://www.iupac.org/>, Livre bleu, Nomenclature des composés organiques

<sup>12</sup> Chemical designation according to the rules of the International Union of Pure and Applied Chemistry (IUPAC), <http://www.iupac.org/>, Blue Book, Nomenclature of Organic Compounds

ANNEX IV: substances to be inserted in Annex IVB

DCI <sup>13</sup> ou nom commun/vulgaire	INN <sup>14</sup> , or common/vernacular name	Nom chimique (Anglais) / Chemical name (English) of la désignation UICPA <sup>15</sup> / IUPAC designation <sup>16</sup>
GABAPENTINE	GABAPENTIN	[1-(aminomethyl)cyclohexyl]acetic acid
PREGABALINE	PREGABALIN	3-(aminomethyl)-5-methylhexanoic acid

Examined for attachment to our Decree of ...

By the King:

The Minister for Public Health,

Frank VANDENBROUCKE

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<sup>13</sup> Dénominations Communes Internationales

<sup>14</sup> International non-proprietary names

<sup>15</sup> Désignation chimique selon les règles de l'Union internationale de chimie pure et appliquée (UICPA), <http://www.iupac.org/>, Livre bleu, Nomenclature des composés organiques

<sup>16</sup> Chemical designation according to the rules of the International Union of Pure and Applied Chemistry (IUPAC), <http://www.iupac.org/>, Blue Book, Nomenclature of Organic Compounds

ANNEX V: Replacement of Annex IVC

<b>Annex IVC:</b>
<i>Preparations listed in the National Plan</i>

Preparations based on:
<b>Tramadol</b>
Where they contain one or more other components
the use or possession of a certified organic product; and
- the quantity of the above mentioned substance does not exceed 400 mg per dosage unit
or
the concentration does not exceed 10% in preparations in undivided form
<b>Pregabalinum</b>
Where they contain one or more other components
the use or possession of a certified organic product; and
- the quantity of the above mentioned substance does not exceed 330 mg per dosage unit
or
- the concentration does not exceed 5% in preparations in undivided form
<b>Gabapentin</b>
Where they contain one or more other components
the use or possession of a certified organic product; and
the quantity of the above mentioned substance does not exceed 800 mg per dosage unit

To be annexed to our Decree of xx xx xxxx.

By the King:

The Minister for Public Health,

Frank VANDENBROUCKE