





DURELA- tramadol hydrochloride capsule, extended release

Galephar Pharmaceutical Research Inc.

Durela 100 mg

GK-232 Rev. 03/2022	Analgésique opioïde Chaque capsule contient : 100 mg de chlorhydrate de tramadol. Contient également du lactose. Dose chez l'adulte : prendre selon les directives exactes du médecin. Avaler les capsules entières. Ne pas briser, mâcher, broyer ou dissoudre. Pour obtenir des renseignements complémentaires, consulter la notice jointe. La monographie est offerte sur demande. Entreposage : entre 15 °C et 30 °C, dans un contenant hermétique. Conserver à l'abri de la lumière, de la moiteur et de l'humidité excessive. Tenir hors de la portée et de la vue des enfants.	Opioid Analgesic Each capsule contains: 100 mg of tramadol hydrochloride. Also contains lactose. Adult Dose: Take exactly as directed. Swallow capsule whole. Do not break, chew, crush, or dissolve. See attached package insert for more information. Product Monograph available on request. Store: 15°C to 30°C in a tight container. Protect from light, moisture, and high humidity. Keep out of reach and sight of children. Cipher Pharmaceuticals Inc., Mississauga, Ontario, L4W 5K9. Concerns / Questions / Problèmes: 1-888-361-7207.	30 Capsules DIN 02373017  Tramadol Hydrochloride Extended-Release Capsules Capsules de chlorhydrate de tramadol à libération prolongée  100 mg LOT: EXP:
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Durela 200 mg

GK-234 Rev. 03/2022	Analgésique opioïde Chaque capsule contient : 200 mg de chlorhydrate de tramadol. Contient également du lactose. Dose chez l'adulte : prendre selon les directives exactes du médecin. Avaler les capsules entières. Ne pas briser, mâcher, broyer ou dissoudre. Pour obtenir des renseignements complémentaires, consulter la notice jointe. La monographie est offerte sur demande. Entreposage : entre 15 °C et 30 °C, dans un contenant hermétique. Conserver à l'abri de la lumière, de la moiteur et de l'humidité excessive. Tenir hors de la portée et de la vue des enfants.	Opioid Analgesic Each capsule contains: 200 mg of tramadol hydrochloride. Also contains lactose. Adult Dose: Take exactly as directed. Swallow capsule whole. Do not break, chew, crush, or dissolve. See attached package insert for more information. Product Monograph available on request. Store: 15°C to 30°C in a tight container. Protect from light, moisture, and high humidity. Keep out of reach and sight of children. Cipher Pharmaceuticals Inc., Mississauga, Ontario, L4W 5K9. Concerns / Questions / Problèmes: 1-888-361-7207.	30 Capsules DIN 02373025  Tramadol Hydrochloride Extended-Release Capsules Capsules de chlorhydrate de tramadol à libération prolongée  200 mg LOT: EXP:
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Durela 300 mg

GK-235
Rev. 03/2022



Analgésique opioïde
Chaque capsule contient :
300 mg de chlorhydrate de tramadol. Contient également du lactose. **Dose chez l'adulte :** prendre selon les directives exactes du médecin. **Avaler les capsules entières. Ne pas briser, mâcher, broyer ou dissoudre.** Pour obtenir des renseignements complémentaires, consulter la notice jointe. La monographie est offerte sur demande. **Entreposage :** entre 15 °C et 30 °C, dans un contenant hermétique. Conserver à l'abri de la lumière, de la moiteur et de l'humidité excessive. Tenir hors de la portée et de la vue des enfants.

Opioid Analgesic
Each capsule contains:
300 mg of tramadol hydrochloride. Also contains lactose. **Adult Dose:** Take exactly as directed. **Swallow capsule whole.** **Do not break, chew, crush, or dissolve.** See attached package insert for more information. Product Monograph available on request. **Store:** 15°C to 30°C in a tight container. Protect from light, moisture, and high humidity. Keep out of reach and sight of children. **Cipher Pharmaceuticals Inc.,** Mississauga, Ontario, L4W 5K9. **Concerns / Questions / Problèmes :** 1-888-361-7207.

30 Capsules

DIN 02373033

Durela[®]

**Tramadol Hydrochloride
Extended-Release Capsules**
**Capsules de chlorhydrate
de tramadol à libération
prolongée**

300 mg



LOT:
EXP:

DURELA

tramadol hydrochloride capsule, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:66277-239
Route of Administration	ORAL	DEA Schedule	CIV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRAMADOL HYDROCHLORIDE (UNII: 9N7R477WCK) (TRAMADOL - UNII:39J1LGJ30)	TRAMADOL HYDROCHLORIDE	100 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONE K30 (UNII: U725QWY32X)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
ETHYL ACRYLATE AND METHYL METHACRYLATE COPOLYMER (2:1; 750000 MW) (UNII: P2OM2Q86BI)	
SUCROSE STEARATE (UNII: 274KW0050M)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TALC (UNII: 7SEV7J4R1U)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	G252;100

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66277-239-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		08/31/2011	

DURELA

tramadol hydrochloride capsule, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:66277-242
Route of Administration	ORAL	DEA Schedule	CIV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRAMADOL HYDROCHLORIDE (UNII: 9N7R477WCK) (TRAMADOL - UNII:39J1LGJ30J)	TRAMADOL HYDROCHLORIDE	300 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONE K30 (UNII: U725QWY32X)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ETHYL ACRYLATE AND METHYL METHACRYLATE COPOLYMER (2:1; 750000 MW) (UNII: P2OM2Q86BI)	
SUCROSE STEARATE (UNII: 274KW0050M)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TALC (UNII: 7SEV7J4R1U)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPRMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	23mm

Flavor		Imprint Code	G254;300	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66277-242-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2011	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
Export only		08/31/2011		

DURELA			
tramadol hydrochloride capsule, extended release			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:66277-241
Route of Administration	ORAL	DEA Schedule	CIV
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TRAMADOL HYDROCHLORIDE (UNII: 9N7R477WCK) (TRAMADOL - UNII:39J1LGJ30J)	TRAMADOL HYDROCHLORIDE	200 mg	
Inactive Ingredients			
Ingredient Name	Strength		
POVIDONE K30 (UNII: U725QWY32X)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
POLYSORBATE 80 (UNII: 6OZP39ZG8H)			
ETHYL ACRYLATE AND METHYL METHACRYLATE COPOLYMER (2:1; 750000 MW) (UNII: P2OM2Q86BI)			
SUCROSE STEARATE (UNII: 274KW0050M)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
TALC (UNII: 7SEV7J4R1U)			
STARCH, CORN (UNII: O8232NY3SJ)			
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)			
Product Characteristics			
Color	white	Score	no score

Shape	CAPSULE	Size	22mm	
Flavor		Imprint Code	G253;200	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66277-241-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2011	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
Export only		08/31/2011		

Labeler - Galephar Pharmaceutical Research Inc. (003551624)

Registrant - Galephar Pharmaceutical Research Inc. (003551624)

Establishment

Name	Address	ID/FEI	Business Operations
Galephar Pharmaceutical Research Inc		003551624	analysis(66277-239, 66277-241, 66277-242) , label(66277-239, 66277-241, 66277-242) , manufacture(66277-239, 66277-241, 66277-242) , pack(66277-239, 66277-241, 66277-242)

Establishment

Name	Address	ID/FEI	Business Operations
Galephar Pharmaceutical Research Inc.		968996160	analysis(66277-239, 66277-241, 66277-242)

Revised: 12/2022

Galephar Pharmaceutical Research Inc.