

## 10 mg & 20 mg (Atorvastatin calcium)

1-Name of the medicinal product: [Jogless' 20 against and quantitative composition [Jogless' 10 aga [Jogless' 10 aga [Jogless' 20 aga [Jogle

3. Pharmaceutical form
Film coated fablet.

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4.2 Posslogs and method of administration

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donace bee section 43. (Condimination with draw maniforms to patients of the condimination with draw maniforms to patients classification and the condimination with draw maniforms to patients behavior agreed education of the condimination o

Use of Mexiculturis not recommended in patients taking elemenor co-administered with cutosporine see sections 44 and 43.)

Heavy and self-sy in patients doler than 70 using recommended does are similar to those seen in the general population.

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Other phermaceulical forms/strengths may be more appropriate for this population.

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bemorthings strate or disture a matu as many sours to be should be carefully considered before initiating treatment lose Section 5x11.

On my a sentral and the potential fish of humorthings doted should be carefully considered before initiating treatment lose Section 5x11.

Abronalatin file other HMA CoA reductace inhibitions, may in rare occasions affect the skeledi muscle and cause modglis, myootils, and moppolity that may progress to trabsdomptoins, a potentially life inherential or continuous files of the mature of the decident of the mature of the decident of the mature of the decident of the mature of the mature of the decident of the mature of the mature of the decident of the mature of t

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Treatine kinses measurement
Treatine kinses (CK) should not be measured following strenuous exercise or in the presence of any plausible alternative cause of CK increase as this makes value interpretation difficult. If CK keets are significantly cleasted at baseline [> 5 times ULN], levels should be remeasured within 5 to 7 days later to confirm the results.

If CA levels are significantly decorded of 5 times ULN at basiseine, becomes should not be started.

Chestica Nature Contractions and Contract

Aboreastish have not been retroached present and the processing of the processing of

and f concomilate administration Canada, we around, pasters behave a several measurement of the properties of the proper e transporters on Alexastatin exposure in hepatocytes is univorse; a commended (see Table 1).

(Alexastatin is not recommended in patients taking letermovir co-administered with ciclosporin (see section 4.4).

for efficacy is recommended one folials 1.

When of Marousdati is not recommended to folial in patients lading letermorie or administered with ciclosporis (see section 4.4).

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Although interaction studies with Alorvastatin and colchicine have not been conducted, cases of myopathy have been reported with Alorvastatin co-colchicine, and caution should be exercised when prescribing Alorvastatin with colchicine.

Although interaction studies with Aironaudatin and colchine have not been conducted, cases of myopatry nate term repense.

Online, and could should be exercised when prescribing Alvanestatin milk colchine.

Iffect of Alonaudatin on co-administered medicinal products.

The control of Alonaudatin on co-administered medicinal products.

Online and the control of Alonaudatin on co-administered medicinal products.

Online and the control of Alonaudatin were co-administered, steady-state digeoin concentrations increased slightly. Patients taking digeoin should be menicleed agreeyinable.

Co-administration of Alonaudatin with an oral contraceptive produced increases in pleana concentrations of norethindrone and chiraly estated.

Co-administration of Alonaudatin with an oral contraceptive produced increases in pleana concentrations of norethindrone and chiraly estated in the control of the control of

Pactating expedition

Drug-drug interaction studies have only been performed in adults. The extent of interactions in the paediatric population is not known. The above mentic
interactions for adults and the warnings in section 44 should be taken into account for the paediatric population.

Drug interactions
Table 1: Fifect of co-administered medicinal products on the pharmacokinetics of Atorvastatin
Co-administered medicinal product

Atorvastatin | Alorvastatin | Dose (mg) | Ratio of AUC<sup>4</sup> | 10 mg OD for 7 days | 8.3 Clinical Recommendation#
Co-administration with products containing and dosing regimen Glecaprevir 400 mg OD/ Pibrentasvir 120 mg OD, 7 days Telaprevir 750 mg q8h, 10 days 20 mg, SD
Ciclosporin 5.2 mg/kg/day, stable dose 10 mg OD for 28 day
copinavir 400 mg BID/ Rifonavir 100 mg BID, 14 days 20 mg OD for 4 days where co-administration with Adoressed Alonsastatin is necessary, lower mainten doses of Alonsastatin are recommended. At Alonsastatin doses exceeding 20 mg dricial monitoring of these patients is recommended. In cases where co-administration with Adoresstatin is necessary, lower maintenances of Alonsastatin doses of Alonsastatin are recommended. At Alonsastatin doses exceeding 40 mg/mical monitoring and along the control of the control larithromycin 500 mg BID, 9 days mg OD for 8 days Darunavir 300 mg BID/ Ritonavir 100 mg BID, 9 days Itraconazole 200 mg OD, 4 days Fosamprenavir 700 mg BID/ Ritonavir 100 mg BID, 10 mg OD for 4 days 40 mg SD 10 mg OD for 4 days 14 days Fosamprenavir 1400 mg BID, 14 days Elbasvir 50 mg OD/ Grazoprevir 200 mg OD, 13 days 10 mg OD for 4 days 10 mg SD The dose of Atorvastatin should not exceed a daily dose of 20 mg during co-administration with products containing elbasvir or grazopre The dose of Atorvastatin should not exceed a daily dose of 20 mg during co-administration with products containing letermovir. Nelfinavir 1250 mg BID, 14 days Grapefruit Juice, 240 mL OD\* 10 mg OD for 28 day 40 mg, SD pefruit juice and a commended.

ter initiation or following dose adjustments of a commended and a commended an Nitiazem 240 mg OD, 28 day 0 mg, SD catients is recommended. Amlodipine 10 mg, single dose Cimetidine 300 mg QID, 2 week Colestipol 10 g BID, 24 weeks 80 mg SD 10 mg OD for 2 weeks 40 mg OD for 8 weeks 10 mg OD for 15 days No specific recommendation.

No specific recommendation 10 mg for 3 days 40 mg SD

\*Secretisms of a ord 4.5 for discission (4.5 prof. inc.).
Creatisms one or more components that inhibit CVTMA and can increase plasma concentrations of medicinal products metabolised by CVTMA. Initiale of one 240 rili gloss of approfinal jaice also resulted in a decreased AUC of 20.4% for the active orthorhorisms profitabolise Large quantities of graphent jaice lower 12.1 daily for 5 specific plasma (20.4%) for the control and an interestinate (3.6%) and (3.6%) interestinate (3.6%) interestinat

\*\* Ratio based on a single sample taken 8-16 h post dose.
On once daily, 50 = single dose; BID = twice daily; TID = three times daily; QID = four times daily.
<u>Table 2: Tifect of Atorvastatin on the pharmarokinetics of co-administered medicinal products</u>

40 mg SD

mg SD

Atorvastatin and dosing	Co-administered medicina		
regimen	Medicinal product/Dose (mg	Ratio of AUC®	Clinical Recommendation
80 mg OD for 10 days	Digoxin 0.25 mg OD, 20 days	1.15	Patients taking digoxin should be monitored
			appropriately.
40 mg OD for 22 days	Oral contraceptive OD, 2 months	1.28	No specific recommendation.
	- norethindrone 1 mg	1.19	
	- ethinyl estradiol 35 µg		
30 mg OD for 15 days	* Phenazone, 600 mg SD	1.03	No specific recommendation.
10 mg, SD	Tipranavir 500 mg BID/ritonavir 200 mg BID, 7 days	1.08	No specific recommendation.
10 mg, OD for 4 days	Fosamprenavir 1400 mg BID, 14 days	0.73	No specific recommendation.
10 mg OD for 4 days	Fosamprenavir 700 mg BID/ritonavir 100 mg BID,	0.99	No specific recommendation.
	14 days		·

iemfibrozil 600 mg BID, 7 days

enofibrate 160 mg OD, 7 days

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Sexual opstantions.
Depression

Operation

Displaces of intentials lung disease, especially with long term through (see section 4.4).
Disblacks Mellitus Frequency will depend on the presence or absence of risk factors (fasting blood glacose ≥ 5.6 mmol/L, BMD-50kg/mZ, raised triglycerides, history

or inperference). 
Reporting of suspected adverse reactions
Reporting of supercited adverse reactions after authorization of the medicinal product is important. It allows continued mentioring of the benefit risk balance of the medicinal product. It follows the professionals are asked to report any suspected adverse reactions to pharmacovigilance center via Pi/followsup@edaegyrt.gov.og
4.70 Overfolose

Secolar Members is not available for Aberostation oversione. Sould an oversione occur. The patient should be invested symptomically and supportive measure instituted, as required. Liver function less should be preferred and seconal Kelevis should be monitored. Due to elemine Abrossalatin brinding to plasmas proteins, beroscidopies is not expected to significantly enhance (Amoustation clearance. S. Armanscologia of properties.)

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The effect of intense legisl towering on major cardiovascular engiones was not investigated in this study. Therefore, the clinical significance of these imaging resussiting and the presention of acodissociate events is subscome.

In the MINCA study, Microsolatin 80 mg has been evaluated in 3,056 patients (Morenstalan m-1538; placedo m-15.48) with an acute convenir yieldness from the study of the study of

| (Alorvastatin vs Placebo) | Absolute Risk | (Alorvastatin vs Placebo) | 83 vs. 127 | 3.2% | 1.9% | 1.9% | 1.3% | Native rainforescalar events that an one-marker of the policy of the pol

		sted in height, weight, BMI				
TABLE 3. Lipid-lov	vering Effects of	Atorvastatin in Adolesce	nt Boys and Girls with He	terozygous Familial		
Hypercholesterole	emia (mmol/L)					
Timepoint	N	TC (S.D.)	LDL-C (S.D.)	HDL-C (S.D.)	TG (S.D.)	Apo B (S.D.)#
Baseline	271	7.86(1.30)	6.12(1.26)	1.314(0.2663)	0.93(0.47)	1.42(0.28)**
Month 30	206	4.95(0.77)*	3.25(0.67)	1.327(0.2796)	0.79(0.38)*	0.90(0.17)*
Month 36/ET	240	5.12(0.86)	3.45(0.81)	1.308(0.2739)	0.78(0.41)	0.93(0.20)***
				sity lipoprotein cholesterol-C;		
'Month 36/ET' incl	luded final visit d	lata for subjects who ende	d participation prior to the	scheduled 36 month timepo	int as well as full 36 mor	nth data for subjects
completing the 36	month participal	tion; ""= Month 30 N for	his parameter was 207; "	**= Baseline N for this param	eter was 270; """ = Mo	nth 36/ET N for this

repoir. Inst-pass metabolism.

Distribution:
Mean volume of distribution of Alorvestatin is approximately 381 L Alorvestatin is > 98% bound to plasma proteins.
Biotarnaformation.

Mean-values of distribution of Morenstatin is approximately 38 1. Neurostatin is a 59% bound to plasma proteins.

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6.2 Incompatibilities
Not appricable
6.3 Shell fill to
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6.5 Shell f

See outer pack for number of strips
6.6 Special precautions for disposal and other handling
No special requirements.
7. License holder & manufacturer name: Amoun pharmaceutical company
8. EDA revision date: june 2025

Keep all medicaments out of reach of children





(أتورفاستاتين كالسيوم)

ترة الملاج - ما الذى تحتاج أن تعرفه قبل تناول عقار ليپيلس". ا تناما: عند لسبكس:

ا با التحد مؤخر المراق من الرحالة المراق مست بعين المست بيسه وهي مست بيسه المست بيسه المراق المراق

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ع الأدوية بعيداً عن متناول الأطفال





