

ABSORICA LD[®] (isotretinoin) Clinical Awareness Resource and Education C-A-R-E[™] Program: Treatment and Patient Monitoring Chart for Healthcare Professionals for Acne Therapy

DISCLAIMER: This material was developed by Sun Pharmaceutical, as part of the risk minimization plan for ABSORICA LD. This material is not intended for promotional use.

Patient Name: _____ Treatment Start Date: _____

This document must be retained in the patient's file for monitoring reference.

	Pretreatment Considerations	At Initiation of Treatment (Start of Month 1)	Start of Month 2	Start of Month 3	Start of Month 4
Patient Assessment (Rate % acne improvement over pretreatment)		<input type="checkbox"/> 25% <input type="checkbox"/> 50% <input type="checkbox"/> 75% <input type="checkbox"/> 100%	<input type="checkbox"/> 25% <input type="checkbox"/> 50% <input type="checkbox"/> 75% <input type="checkbox"/> 100%	<input type="checkbox"/> 25% <input type="checkbox"/> 50% <input type="checkbox"/> 75% <input type="checkbox"/> 100%	<input type="checkbox"/> 25% <input type="checkbox"/> 50% <input type="checkbox"/> 75% <input type="checkbox"/> 100%
Dosage	<ul style="list-style-type: none"> The initial dose of ABSORICA LD should be individualized according to the patient's weight and severity of the disease. Note that transient exacerbation of acne is occasionally seen during this initial period A complete course of therapy consists of 15 to 20 weeks of ABSORICA LD administration Please consult Product Monograph for complete dosage and administration instructions 	<ul style="list-style-type: none"> Usual dose range is between 0.4 to 0.8 mg/kg body weight daily ABSORICA LD may be taken with or without meals, as a single daily dose or in 2 divided doses ABSORICA LD should be taken in the nearest number of whole capsules, either as a single dose or in 2 divided doses during the day, whichever is more convenient. To decrease the risk of esophageal irritation, instruct patients to take the capsules with a full glass of liquid For females, treatment should start on the second or third day of the next normal menstrual period following the second negative pregnancy test 	<ul style="list-style-type: none"> The dose should be adjusted between 0.4 and 0.8 mg/kg body weight daily. In exceptional instances, dosage may be adjusted up to 1.6 mg/kg/day depending upon individual patient response and tolerance to the drug. ABSORICA LD may be taken with or without meals, as a single daily dose or in 2 divided doses ABSORICA LD should be taken in the nearest number of whole capsules, either as a single dose or in 2 divided doses during the day, whichever is more convenient. To decrease the risk of esophageal irritation, instruct patients to take the capsules with a full glass of liquid Dosage depends on individual patient response and tolerance to the drug Review any side effects and adjust dosage as required 	<ul style="list-style-type: none"> The dose should be adjusted between 0.4 and 0.8 mg/kg body weight daily. In exceptional instances, dosage may be adjusted up to 1.6 mg/kg/day depending upon individual patient response and tolerance to the drug. ABSORICA LD may be taken with or without meals, as a single daily dose or in 2 divided doses ABSORICA LD should be taken in the nearest number of whole capsules, either as a single dose or in 2 divided doses during the day, whichever is more convenient. To decrease the risk of esophageal irritation, instruct patients to take the capsules with a full glass of liquid Dosage depends on individual patient response and tolerance to the drug Review any side effects and adjust dosage as required 	<ul style="list-style-type: none"> The dose should be adjusted between 0.4 and 0.8 mg/kg body weight daily. In exceptional instances, dosage may be adjusted up to 1.6 mg/kg/day depending upon individual patient response and tolerance to the drug. ABSORICA LD may be taken with or without meals, as a single daily dose or in 2 divided doses ABSORICA LD should be taken in the nearest number of whole capsules, either as a single dose or in 2 divided doses during the day, whichever is more convenient. To decrease the risk of esophageal irritation, instruct patients to take the capsules with a full glass of liquid Dosage depends on individual patient response and tolerance to the drug Review any side effects and adjust dosage as required
Female patients only	<ul style="list-style-type: none"> Use effective contraception without any interruption for 1 month before beginning ABSORICA LD therapy Two reliable forms of contraception should be used simultaneously (at least one being a primary method), even by female patients who normally do not employ contraception due to infertility, who are not sexually active, or who have amenorrhea Two negative serum or urine pregnancy tests before starting ABSORICA LD therapy Treatment should start on the second or third day of the next normal menstrual period following the second negative pregnancy test Review the C-A-R-E Program No breastfeeding during treatment 	<input type="checkbox"/> Patient confirms having used effective contraception without any interruption during ABSORICA LD therapy <ul style="list-style-type: none"> Two reliable forms of contraception should be used simultaneously (at least one being a primary method), even by female patients who normally do not employ contraception due to infertility, who are not sexually active, or who have amenorrhea <input type="checkbox"/> Before renewal of prescription, obtained confirmation from patient of negative serum or urine pregnancy test made no more than 1 week before prescription renewal visit <ul style="list-style-type: none"> Review the C-A-R-E Program No breastfeeding during treatment 	<input type="checkbox"/> Patient confirms having used effective contraception without any interruption during ABSORICA LD therapy <ul style="list-style-type: none"> Two reliable forms of contraception should be used simultaneously (at least one being a primary method), even by female patients who normally do not employ contraception due to infertility, who are not sexually active, or who have amenorrhea <input type="checkbox"/> Before renewal of prescription, obtained confirmation from patient of negative serum or urine pregnancy test made no more than 1 week before prescription renewal visit <ul style="list-style-type: none"> Review the C-A-R-E Program No breastfeeding during treatment 	<input type="checkbox"/> Patient confirms having used effective contraception without any interruption during ABSORICA LD therapy <ul style="list-style-type: none"> Two reliable forms of contraception should be used simultaneously (at least one being a primary method), even by female patients who normally do not employ contraception due to infertility, who are not sexually active, or who have amenorrhea <input type="checkbox"/> Before renewal of prescription, obtained confirmation from patient of negative serum or urine pregnancy test made no more than 1 week before prescription renewal visit <ul style="list-style-type: none"> Review the C-A-R-E Program No breastfeeding during treatment 	<input type="checkbox"/> Confirms having used effective contraception without any interruption during ABSORICA LD therapy and has been warned to continue to do so for 1 month after treatment ends <ul style="list-style-type: none"> Two reliable forms of contraception should be used simultaneously (at least one being a primary method), even by female patients who normally do not employ contraception due to infertility, who are not sexually active, or who have amenorrhea <input type="checkbox"/> Before renewal of prescription, obtained confirmation from patient of negative serum or urine pregnancy test made no more than 1 week before prescription renewal visit and reminded patient to also do such a test at 1 month after discontinuation of treatment <ul style="list-style-type: none"> Review the C-A-R-E Program No breastfeeding during treatment and for 1 month after discontinuation of treatment

Warnings and Precautions

	Pretreatment Considerations	At Initiation of Treatment (Start of Month 1)	Start of Month 2	Start of Month 3	Start of Month 4
Warnings and Precautions	<ul style="list-style-type: none"> Do not donate blood or blood products Do not share ABSORICA LD with other people Do not take antibiotics (such as tetracyclines) unless discussed with doctor Do not take vitamin A supplements Use sun protection and avoid artificial UV lights Abstain from/minimize alcohol consumption Do not use exfoliative anti-acne agents or have cosmetic procedures to smooth the skin such as waxing, aggressive chemical dermabrasion, cutaneous laser procedures, or wax epilation until 5 to 6 months after the end of treatment Do not take St. John's wort Avoid strenuous physical activity or vigorous exercise Do not drive at night until you know if ABSORICA LD has affected your vision Do not change between ABSORICA LD and other isotretinoin products. ABSORICA LD is not the same as other isotretinoin products Do not use ABSORICA LD for a condition for which it was not prescribed Do not take low-dose birth control pills that contain progesterone only Do not take corticosteroids such as hydrocortisone, prednisolone, etc Do not take phenytoin 	<ul style="list-style-type: none"> Complete lab testing 1 week prior to visit Do not donate blood or blood products Do not share ABSORICA LD with other people Do not take antibiotics (such as tetracyclines) unless discussed with doctor Do not take vitamin A supplements Use sun protection and avoid artificial UV lights Abstain from/minimize alcohol consumption Do not use exfoliative anti-acne agents or have cosmetic procedures to smooth the skin such as waxing, aggressive chemical dermabrasion, cutaneous laser procedures, or wax epilation until 5 to 6 months after the end of treatment Do not take St. John's wort Avoid strenuous physical activity or vigorous exercise Do not drive at night until you know if ABSORICA LD has affected your vision Do not change between ABSORICA LD and other isotretinoin products. 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UV, ultraviolet.

Blood Monitoring

	Pretreatment Considerations	At Initiation of Treatment (Start of Month 1)	Start of Month 2	Start of Month 3	Start of Month 4
Blood monitoring	Complete blood count	Complete blood count	Complete blood count	Complete blood count	Complete blood count
	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal
	Blood sugar (diabetics)	Blood sugar (diabetics)	Blood sugar (diabetics)	Blood sugar (diabetics)	Blood sugar (diabetics)
	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal
	Urine or serum pregnancy	Urine or serum pregnancy	Urine or serum pregnancy	Urine or serum pregnancy	Urine or serum pregnancy
	<input type="checkbox"/> Negative <input type="checkbox"/> Positive	<input type="checkbox"/> Negative <input type="checkbox"/> Positive	<input type="checkbox"/> Negative <input type="checkbox"/> Positive	<input type="checkbox"/> Negative <input type="checkbox"/> Positive	<input type="checkbox"/> Negative <input type="checkbox"/> Positive
	Lipids	Lipids	Lipids	Lipids	Lipids
	Triglycerides*	Triglycerides*	Triglycerides*	Triglycerides*	Triglycerides*
	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal
	Cholesterol	Cholesterol	Cholesterol	Cholesterol	Cholesterol
	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal
	HDL	HDL	HDL	HDL	HDL
	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal
	LDL	LDL	LDL	LDL	LDL
	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal
	Liver Function	Liver Function	Liver Function	Liver Function	Liver Function
	ALT	ALT	ALT	ALT	ALT
	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal
	AST	AST	AST	AST	AST
	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal
ALP	ALP	ALP	ALP	ALP	
<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	
Renal Function	Renal Function	Renal Function	Renal Function	Renal Function	
<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	

ALT, alanine transaminase; AST, aspartate aminotransferase; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

*There have been some reports of acute pancreatitis, which is known to be potentially fatal. This is sometimes associated with elevation of serum triglycerides in excess of 800 mg/dL or 9 mmol/L. Therefore, every attempt should be made to control significant triglyceride elevation. ABSORICA LD should be discontinued if uncontrolled hypertriglyceridemia or symptoms of pancreatitis occur. Abnormalities of serum triglycerides, HDL, and cholesterol were reversible upon cessation of oral isotretinoin therapy.

Side-Effect Management

	Pretreatment Considerations	At Initiation of Treatment (Start of Month 1)	Start of Month 2	Start of Month 3	Start of Month 4
Serious side-effect management For other possible side effects, please consult the Product Monograph for information.		Side-effect counselling Serious side effects* <input type="checkbox"/> Mental health problems such as depression or psychosis <input type="checkbox"/> Liver problems <input type="checkbox"/> Pancreatitis <input type="checkbox"/> Intestine (bowel) problems <input type="checkbox"/> Bone and muscle problems <input type="checkbox"/> Allergic reactions <input type="checkbox"/> Benign intracranial hypertension <input type="checkbox"/> Hearing and vision problems <input type="checkbox"/> Heart problems <input type="checkbox"/> Pregnancy issues during or after treatment <input type="checkbox"/> Problems with blood sugar levels <input type="checkbox"/> Serious skin reactions such as erythema multiforme (EM), Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN)	Side-effect counselling Serious side effects* <input type="checkbox"/> Mental health problems such as depression or psychosis <input type="checkbox"/> Liver problems <input type="checkbox"/> Pancreatitis <input type="checkbox"/> Intestine (bowel) problems <input type="checkbox"/> Bone and muscle problems <input type="checkbox"/> Allergic reactions <input type="checkbox"/> Benign intracranial hypertension <input type="checkbox"/> Hearing and vision problems <input type="checkbox"/> Heart problems <input type="checkbox"/> Pregnancy issues during or after treatment <input type="checkbox"/> Problems with blood sugar levels <input type="checkbox"/> Serious skin reactions such as erythema multiforme (EM), Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN)	Side-effect counselling Serious side effects* <input type="checkbox"/> Mental health problems such as depression or psychosis <input type="checkbox"/> Liver problems <input type="checkbox"/> Pancreatitis <input type="checkbox"/> Intestine (bowel) problems <input type="checkbox"/> Bone and muscle problems <input type="checkbox"/> Allergic reactions <input type="checkbox"/> Benign intracranial hypertension <input type="checkbox"/> Hearing and vision problems <input type="checkbox"/> Heart problems <input type="checkbox"/> Pregnancy issues during or after treatment <input type="checkbox"/> Problems with blood sugar levels <input type="checkbox"/> Serious skin reactions such as erythema multiforme (EM), Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN)	Side-effect counselling Serious side effects* <input type="checkbox"/> Mental health problems such as depression or psychosis <input type="checkbox"/> Liver problems <input type="checkbox"/> Pancreatitis <input type="checkbox"/> Intestine (bowel) problems <input type="checkbox"/> Bone and muscle problems <input type="checkbox"/> Allergic reactions <input type="checkbox"/> Benign intracranial hypertension <input type="checkbox"/> Hearing and vision problems <input type="checkbox"/> Heart problems <input type="checkbox"/> Pregnancy issues during or after treatment <input type="checkbox"/> Problems with blood sugar levels <input type="checkbox"/> Serious skin reactions such as erythema multiforme (EM), Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN)
Nuisance side-effect management	Side-effect counselling Common side effects* <input type="checkbox"/> Chapped lips <input type="checkbox"/> Dryness of lining of nose <input type="checkbox"/> Dry skin or itching <input type="checkbox"/> Arthralgia <input type="checkbox"/> Myalgia <input type="checkbox"/> Other _____ _____	Side-effect counselling Common side effects* <input type="checkbox"/> Chapped lips <input type="checkbox"/> Dryness of lining of nose <input type="checkbox"/> Dry skin or itching <input type="checkbox"/> Arthralgia <input type="checkbox"/> Myalgia <input type="checkbox"/> Other _____ _____	Side-effect counselling Common side effects* <input type="checkbox"/> Chapped lips <input type="checkbox"/> Dryness of lining of nose <input type="checkbox"/> Dry skin or itching <input type="checkbox"/> Arthralgia <input type="checkbox"/> Myalgia <input type="checkbox"/> Other _____ _____	Side-effect counselling Common side effects* <input type="checkbox"/> Chapped lips <input type="checkbox"/> Dryness of lining of nose <input type="checkbox"/> Dry skin or itching <input type="checkbox"/> Arthralgia <input type="checkbox"/> Myalgia <input type="checkbox"/> Other _____ _____	Side-effect counselling Common side effects* <input type="checkbox"/> Chapped lips <input type="checkbox"/> Dryness of lining of nose <input type="checkbox"/> Dry skin or itching <input type="checkbox"/> Arthralgia <input type="checkbox"/> Myalgia <input type="checkbox"/> Other _____ _____
Suggested treatments for nuisance side effects	<ul style="list-style-type: none"> • Dryness of lining of nose: Apply nasal lubricant • Arthralgia: Treat with acetaminophen or NSAIDs • Myalgia: Treat with acetaminophen or NSAIDs 		<ul style="list-style-type: none"> • Chapped lips: Apply a lip balm • Dry skin or itching: Apply a water-based moisturizer • Dryness of eyes: Use an artificial tears product 		<ul style="list-style-type: none"> • Exacerbation of acne is usually transient
Other considerations	Questions for patients Mood swings? <input type="checkbox"/> Yes <input type="checkbox"/> No Depression? <input type="checkbox"/> Yes <input type="checkbox"/> No	Questions for patients Mood swings? <input type="checkbox"/> Yes <input type="checkbox"/> No Depression? <input type="checkbox"/> Yes <input type="checkbox"/> No	Questions for patients Mood swings? <input type="checkbox"/> Yes <input type="checkbox"/> No Depression? <input type="checkbox"/> Yes <input type="checkbox"/> No	Questions for patients Mood swings? <input type="checkbox"/> Yes <input type="checkbox"/> No Depression? <input type="checkbox"/> Yes <input type="checkbox"/> No	Questions for patients Mood swings? <input type="checkbox"/> Yes <input type="checkbox"/> No Depression? <input type="checkbox"/> Yes <input type="checkbox"/> No

NSAIDs, nonsteroidal anti-inflammatory drugs.

*Other possible side effects—please consult the Product Monograph for information.