



Supply chain disruption report

Eugia Unit 3 manufacturing facility in Hyderabad, India

Situation

Eugia Pharma Specialties Ltd. has voluntarily paused manufacturing at their Unit 3 facility in Hyderabad, India.

Background

Eugia, a wholly owned subsidiary of Aurobindo, has voluntarily paused production at Unit 3, a formulation manufacturing facility, following an FDA inspection. FDA inspected the facility from January 22 to February 2, 2024. In [response to an inquiry](#), the company noted production was paused at the facility on February 2. The pause in production followed the closing of the inspection with 9 observations recorded by FDA. In the response, the company noted temporarily pausing manufacturing on certain lines to conduct a thorough investigation. Per communication with Eugia, the company is actively working with FDA and a third-party consultant to accelerate the process and resume manufacturing.

On February 5, Eugia identified products ([Appendix 3](#)) via a customer letter that will be affected by the pause in the production.

While production is temporarily paused, Eugia encourages procurement of product normally as the assessment of the facility continues.

The End Drug Shortages Alliance (EDSA) would like to acknowledge that the information provided in this document was compiled on behalf of its Rapid Response Team (RRT) in collaboration with the Vizient® Center for Pharmacy Practice Excellence and the United States Pharmacopoeia (USP). To learn more about the RRT, or to be involved, please visit [Appendix 4](#) of this document.

Assessment

Market analysis

The included market analysis in [Appendix 1](#) and [Appendix 2](#) outlines the identified subset of Eugia products provided in the Eugia customer letter that may experience continued or new supply disruptions due to the pause in production at the Unit 3 facility. Per a Eugia customer letter on February 5, this subset is based on specific products manufactured at the Unit 3 facility as provided in [Appendix 3](#).

Of the 57 NDCs provided by Eugia in their customer letter, the market analysis is at the presentation level, of which there are 36 unique molecules. **Eugia is not the sole manufacturer for any affected product.** The market analysis identifies essential medications, mitigation strategies, and additional manufacturers in the market. The market shares provided in [Appendix 1](#) and [Appendix 2](#) are based on total Eugia eaches sold, regardless of manufacturing site.

Included in these analyses is the [USP Supply Chain Vulnerability Score](#), which provides information at the product level for products that are susceptible to future drug shortages.

Recommendations

Manufacturers

The End Drug Shortages Alliance (EDSA) recommends that sterile injectable manufacturers and 503B compounders of impacted products and their alternatives evaluate their ability to increase production to help meet current demand levels for products. Furthermore, the EDSA advocates for comprehensive dialogue between all manufacturers and wholesalers to establish suitable allocations for affected products and their alternatives. We also urge strict adherence to best practices, distribution, and allocation channels. As impacted product lists become available, 503B

compounders may consider reviewing their formularies to assess production capabilities for impacted essential medications where possible.

When production at the Eugia facility resumes, the EDSA recommends to Eugia the prioritization of essential medications, for which Eugia has a high market share or is currently experiencing supply challenges.

Wholesalers

The EDSA recommends that wholesalers communicate with manufacturers and establish protective allocations (e.g., 120%) for impacted products and their alternatives to ensure the product is available for patient care and refine as more information is available. The EDSA recommends that wholesalers maintain relevant allocations in place until additional information is available on product specific market impact.

Group Purchasing Organizations

The EDSA encourages Group Purchasing Organizations (GPOs) to consider novel sourcing strategies to provide their members with additional redundancy for essential medications to minimize potential patient care disruption. Further, we recommend they communicate regularly with supply chain leaders to support access and resiliency.

Clinical Providers

The EDSA encourages providers and clinicians to exercise the principles of [drug shortage stewardship](#) and [calls to action](#) when ordering, prescribing, and administering medications affected by supply constraints to preserve availability for vulnerable patient populations. Alert your regulatory community with any price gouging or predatory activity.


Mitigation strategies for select products are provided in [Appendix 1](#) and [Appendix 2](#). The strategies were developed in coordination with the Vizient® Center for Pharmacy Practice Excellence to provide peer-reviewed validation of the mitigation recommendations.

The USP Vulnerability Score

The USP Vulnerability Score measures the likelihood of future drug product shortage, and a greater score indicates higher risk. These scores do not yet consider the impact of Eugia’s pause in production and should be treated as a measure of pre-existing supply chain vulnerability. The Vulnerability Score is based on a model that incorporates several features, including the location of manufacturing, inspection records of manufacturing facilities, economic and market factors as well as drug characteristics such as dosage form and complexity of manufacturing. The USP Vulnerability Score is back tested using drug shortage data from the American Society of Health-System Pharmacists (ASHP) and the Food and Drug Administration (FDA). Learn more [here](#).

Appendix 1. Market analysis of Eugia products with manufacturing temporarily paused^a

Table 1. Products with Eugia market share > 50%

Drug Product	Eugia Market Share of Presentation(s) Affected ^{b-d}	USP Supply Chain Vulnerability Score ^e
Acyclovir injection  500 mg/10 mL (50 mg/mL), 1 g/20 mL (50 mg/mL)	53%	29%
Esmolol hydrochloride injection 100 mg/10 mL (10 mg/mL)	74% ^f	26%



Polymyxin B injection  500,000 units	55%	15%
Vecuronium bromide injection  10 mg, 20 mg	54%	95%

Table 2. Products with Eugia market share 10-50%


















Drug Product	Eugia Market Share of Presentation(s) Affected ^{b-d}	USP Supply Chain Vulnerability Score ^e
Acetylcysteine injection  6 g/ 30mL (200 mg/mL)	27%	14%
Azithromycin injection  500 mg	45%	38%
Eptifibatide injection  75 mg/100 mL (0.75 mg/mL), 20 mg/10 mL (2 mg/mL), 200 mg/100 mL (2 mg/mL)	16%	95%
Fluphenazine decanoate injection 125 mg/5 mL (25 mg/mL)	24%	20%
Fondaparinux sodium injection 2.5 mg/0.5 mL, 5 mg/0.4 mL, 7.5 mg/0.6 mL, 10 mg/0.8 mL	23%	25%
Ibandronate sodium PF injection 3 mg/3 mL (1 mg/mL)	13%	12%
Methocarbamol injection 1000 mg/10 mL (100 mg/mL)	16%	20%
Nicardipine hydrochloride injection  25 mg/10 mL (2.5 mg/mL)	40%	22%
Olanzapine injection 10 mg	36%	88%
Pantoprazole injection  40 mg	38%	92%
Rocuronium bromide injection  50 mg/5 mL (10 mg/mL), 100 mg/ 10 mL (10 mg/mL)	24%	97%
Sumatriptan injection 6 mg/0.5 mL	17%	23%
Vasopressin injection  20 units/1 mL	32%	34%

Table 3. Products with Eugia market share < 10%

Drug Product	Eugia Market Share of Presentation(s) Affected ^{b-d}	USP Supply Chain Vulnerability Score ^e
Bivalirudin injection 250 mg	6%	37%
Carboprost tromethamine injection 250 mcg/mL	1%	27%
Daptomycin injection  500 mg	4%	31%
Dexamethasone sodium phosphate injection  120 mg/30 mL (4 mg/mL), 100 mg/10 mL (10 mg/mL)	2% ^g	97%
Dexamethasone sodium phosphate PF injection  10 mg/1 mL	2% ^g	97%
Diltiazem hydrochloride injection  25 mg/5 mL (5 mg/mL), 50 mg/10 mL (5 mg/mL), 125 mg/25 mL (5 mg/mL)	5%	88%
Doxercalciferol injection 4 mcg/2 mL	2%	44%
Fosaprepitant dimeglumine injection 150 mg	1%	28%
Hydralazine hydrochloride injection 20 mg/mL	1%	39%
Isoproterenol hydrochloride injection  0.2 mg/1mL, 1 mg/5 mL (0.2 mg/mL)	1%	19%
Methylprednisolone acetate injection 400 mg/10 mL (40 mg/mL), 400 mg/5 mL (80 mg/mL)	1%	89%
Naloxone hydrochloride PF injection  2 mg/2 mL (1 mg/mL)	7% ^h	32%
Naloxone hydrochloride injection  0.4 mg/1 mL, 4 mg/10 mL (0.4 mg/mL)	7% ^h	32%
Posaconazole injection 300 mg/16.7 mL (18 mg/mL)	NA	N/A
Thiamine injection  200 mg/2 mL (100 mg/mL)	4%	53%

Tigecycline injection  50 mg	7%	25%
Tobramycin sulfate injection 1.2 g/vial	1%	38%
Triamcinolone acetonide injection 200 mg/5 mL (40 mg/mL), 400 mg/10 mL (40 mg/mL)	1%	19%
Vancomycin hydrochloride injection  1.25 g/vial and 1.5 g/vial	2%	95%

PF = preservative-free

^aMarket shares are calculated based on total Eugia eaches sold and represent various product presentations, regardless of manufacturing site.

^bIQVIA analysis at the level of drug name and dosage form (e.g., inhalation, injection, intrathecal), unless otherwise specified; includes year-to-date 2023 (January 2023 to December 2023); suppliers where market share < 1% excluded and Akorn market share excluded. Calculated using eaches sold.

^cThe term “eaches” represents the number of single items (such as vials, syringes, bottles, or packet of pills) contained in a unit or shipping package and purchased by pharmacies in a specific time period. An each is not a single pill or dosage of medicine (unless one package consists of a single dose). An each may be the same as a unit if the unit does not subdivide into packages. A “unit” refers to the total amount of packages sold of a particular drug to the dispensing outlet/chain/hospital.

^dDoes not include 503b market share information.

^eVulnerability scores obtained from the [USP Supply Map](#)

^fincludes all injectable esmolol products available on the market

^gIncludes all injectable dexamethasone products available on the market

^hIncludes all injectable naloxone products available on the market

 = Essential Medication on the [Vizient Essential Medication List](#)

Appendix 2. Guidance for products with significant Eugia market share^{a-c}

Drug Product	Mitigation Strategy
Acetylcysteine injection	<ul style="list-style-type: none"> Implement EHR decision support to direct ordering providers to appropriate alternatives when possible. Reserve parenteral acetylcysteine for cases of acetaminophen toxicity where treatment with oral acetylcysteine is not appropriate. Utilize oral acetylcysteine when possible. Additional guidance is available in the following reference: <ul style="list-style-type: none"> 2023 Consensus statement for treatment of acetaminophen toxicity
Acyclovir injection	<ul style="list-style-type: none"> Implement EHR decision support to direct ordering provider to appropriate alternatives when possible. Convert to oral formulations based on clinical picture and consider restricting use to high-risk populations (eg, neonates, pregnant women, patients with CNS infections, or those for whom alternatives are not appropriate).
Azithromycin injection	<ul style="list-style-type: none"> Implement EHR decision support to direct ordering providers to appropriate alternatives when possible. Reserve parenteral azithromycin for cases in which other alternatives are not available. Utilize oral azithromycin when possible. Utilize appropriate parenteral antibiotic alternatives as needed, determined by the site of infection and suspected micro-organisms. <ul style="list-style-type: none"> Example of alternative antibiotic for regimen using parenteral azithromycin: <ul style="list-style-type: none"> Community-acquired pneumonia requiring hospitalization: a respiratory fluoroquinolone (in place of azithromycin) may be used in combination with a beta-lactam antibiotic.
Eptifibatide injection	<ul style="list-style-type: none"> Implement EHR decision support to direct ordering providers to appropriate alternatives when possible. If a GPI is necessary, consider tirofiban as an alternative small molecule GPI.
Esmolol hydrochloride injection	<ul style="list-style-type: none"> Implement EHR decision support to direct ordering providers to appropriate alternatives when possible.

	<ul style="list-style-type: none"> Reserve esmolol for use in cases where a short-acting, intravenous beta-blocker is desired (eg, management of intraoperative sinus tachycardia and for selected pediatric and neonatal cases). If an intravenous beta-blocker is needed, use alternative intravenous beta-blockers where possible. Use alternative agents for the treatment of hypertensive emergencies (eg, calcium channel blockers, nitrates) as appropriate depending patient specific factors.
Fluphenazine decanoate injection	<ul style="list-style-type: none"> Implement EHR decision support to direct ordering providers to appropriate alternatives when possible. Utilize oral fluphenazine if possible. Schedule patients receiving fluphenazine on the same day to minimize wastage. If long-acting parenteral therapy is required, consider alternative long-acting injectable antipsychotic agents after an adequate trial of the respective oral formulation per manufacturer's guidance.
Fondaparinux sodium injection	<ul style="list-style-type: none"> Implement EHR decision support to direct ordering providers to appropriate alternatives when possible. Reserve fondaparinux sodium for patients with 1) acute HIT complicated by thrombosis or acute HIT without thrombosis, 2) remote HIT who require VTE treatment or prophylaxis, and 3) spontaneous superficial vein thrombosis. As an alternative for HIT treatment, consider non-heparin anticoagulants such as argatroban, bivalirudin, or direct-acting oral anticoagulants. The choice of agent may be influenced by drug factors, patient factors, and the experience of the clinician. As an alternative for VTE treatment or prophylaxis for patients with remote HIT, consider non-heparin anticoagulants such as apixaban, dabigatran, edoxaban, rivaroxaban, or warfarin. As an alternative for the treatment of spontaneous superficial vein thrombosis, consider rivaroxaban. For most other clinical scenarios, including VTE prophylaxis or treatment, consider a low-molecular weight heparin or direct-acting oral anticoagulants depending on the clinical scenario.
Methocarbamol injection	<ul style="list-style-type: none"> Implement EHR decision support to direct ordering providers to appropriate alternatives when possible. Utilize oral methocarbamol or another skeletal muscle relaxant when possible (eg, carisoprodol, cyclobenzaprine, metaxalone, tizanidine, etc). If parenteral therapy is required, consider orphenadrine.
Nicardipine hydrochloride injection	<ul style="list-style-type: none"> Reserve nicardipine for use in cases where intravenous blood pressure management is required (eg, management of hypertensive emergency). If an intravenous calcium channel blocker is needed, utilize clevidipine where possible. Use alternative agents for the treatment of hypertensive emergencies (eg, beta blockers, nitrates) as appropriate depending patient specific factors. Implement EHR decision support to direct ordering providers to appropriate alternatives when possible.
Olanzapine injection	<ul style="list-style-type: none"> Implement EHR decision support to direct ordering providers to appropriate alternatives when possible. Utilize oral olanzapine or other oral agents when possible. If parenteral therapy is required, consider droperidol, haloperidol lactate, or ziprasidone when clinically appropriate.
Pantoprazole injection	<ul style="list-style-type: none"> Implement EHR decision support to direct ordering providers to alternatives when possible. Utilize oral proton pump inhibitors when possible. If parenteral therapy is required, use alternative proton pump inhibitors such as esomeprazole.
Polymyxin B injection	<ul style="list-style-type: none"> Reserve polymyxin B injection for patients with multidrug resistant infections, for which other alternatives are not an option. Additional guidance is available in the following references: <ul style="list-style-type: none"> 2019 International Consensus for the optimal use of polymyxins 2023 IDSA guidance on the treatment of antimicrobial resistant gram-negative infections
Rocuronium bromide injection	<ul style="list-style-type: none"> Consider other available neuromuscular blocking agents as clinically appropriate.
Sumatriptan injection	<ul style="list-style-type: none"> Implement EHR decision support to direct ordering providers to appropriate alternatives when possible.

	<ul style="list-style-type: none"> Utilize oral sumatriptan or other oral serotonin 5-HT_{1B, 1D} antagonists or oral calcitonin gene-related peptide antagonists when possible. If oral medications are not an option, consider intranasal sumatriptan, zolmitriptan, or zavegepant or parenteral dihydroergotamine, prochlorperazine, metoclopramide, chlorpromazine, valproate, or ketorolac when clinically appropriate.
Vasopressin injection	<ul style="list-style-type: none"> Reserve vasopressin as an adjunctive agent for septic shock and other vasodilatory shock states. For adults, consider utilizing vasopressin for septic shock when the goal MAP of 65 mm Hg is not achieved with initial fluid resuscitation and first-line norepinephrine use. For pediatrics, consider adding vasopressin or further titrating catecholamines in children with septic shock who require high-dose catecholamines. Additional guidance is available in the following reference: <ul style="list-style-type: none"> 2021 Surviving sepsis campaign for the optimal use of vasopressin in septic shock 2020 Surviving sepsis campaign for children
Vecuronium bromide injection	<ul style="list-style-type: none"> Consider other available neuromuscular blocking agents as clinically appropriate.

CNS = central nervous system, EHR = electronic health record, GPI = glycoprotein inhibitor, HIT = heparin induced thrombocytopenia, MAP = mean arterial pressure, VTE = venous thromboembolism

^aMarket shares are calculated based on total Eugia eaches sold and represent various product presentations, regardless of manufacturing site.

^bIQVIA analysis at the level of drug name and dosage form (e.g., inhalation, injection, intrathecal), unless otherwise specified; includes year-to-date 2023 (January 2023 to December 2023); suppliers where market share < 1% excluded and Akorn market share excluded. Calculated using eaches sold.

^cThe term “eaches” represents the number of single items (such as vials, syringes, bottles, or packet of pills) contained in a unit or shipping package and purchased by pharmacies in a specific time period. An each is not a single pill or dosage of medicine (unless one package consists of a single dose). An each may be the same as a unit if the unit does not subdivide into packages. A “unit” refers to the total amount of packages sold of a particular drug to the dispensing outlet/chain/hospital.

Appendix 3. Eugia products for which manufacturing is temporarily paused

NDC	Product Description
55150-0259-30	Acetylcysteine 6 g/30 mL (200 mg/mL, 20 %) single-dose vial
55150-0154-10	Acyclovir sodium 500 mg/ 10 mL (50 mg/mL) vial
55150-0155-20	Acyclovir sodium 1 g/ 20 mL (50 mg/mL) vial
55150-0174-10	Azithromycin injection USP 500 mg vial
55150-0210-10	Bivalirudin injection 250 mg single-dose vial
55150-0459-10	Carboprost tromethamine injection 250 mcg/mL vial
55150-0344-01	Daptomycin injection 500 mg single-dose vial
55150-0305-10	Dexamethasone sodium phosphate USP 100 mg/10 mL (10 mg/mL) multi-dose vial
55150-0239-30	Dexamethasone sodium phosphate USP 120 mg/30 mL (4 mg/mL) multi-dose vial
55150-0304-25	Dexamethasone sodium phosphate/PF 10 mg/mL single-dose vial
55150-0425-10	Diltiazem HCl 25 mg/5 mL (5 mg/mL) vial
55150-0426-10	Diltiazem HCl 50 mg/10 mL (5 mg/mL) vial
55150-0427-10	Diltiazem HCl 125 mg/25 mL (5 mg/mL) vial
55150-0359-50	Doxercalciferol injection 4 mcg/2 mL multi-dose vial

55150-0219-10	Eptifibatide injection 20 mg/10 mL (2 mg/mL) single-dose vial
55150-0220-99	Eptifibatide 200 mg/100 mL (2 mg/mL) single-dose vial
55150-0218-99	Eptifibatide 75 mg/100 mL (0.75 mg/mL) single-dose vial
55150-0194-10	Esmolol HCl 100 mg/10 mL (10 mg/mL) vial
55150-0267-05	Fluphenazine decanoate injection USP 125 mg/5 mL (25 mg/mL) multi-dose vial
55150-0233-10	Fondaparinux sodium injection PF 10 mg/0.8 mL syringe
55150-0230-10	Fondaparinux sodium injection PF 2.5 mg/0.5 mL syringe
55150-0231-10	Fondaparinux sodium injection PF 5 mg/0.4 mL syringe
55150-0232-10	Fondaparinux sodium injection PF 7.5 mg/0.6 mL syringe
55150-0299-01	Fosaprepitant dimeglumine injection 150 mg single-dose vial
55150-0400-25	Hydralazine hydrochloride injection USP 20 mg/mL vial
55150-0191-83	Ibandronate sodium injection PF 3 mg/3 mL (1 mg/mL) syringe
55150-0317-10	Isoproterenol hydrochloride injection USP 1 mg/5 mL (0.2 mg/mL) ampule
55150-0316-25	Isoproterenol hydrochloride injection USP 0.2 mg/mL ampule
55150-0223-10	Methocarbamol 100 mg/mL USP injection 1000 mg/10 mL (10 mg/mL) single-dose vial
55150-0313-01	Methylprednisolone acetate injection USP 400 mg/10 mL (40 mg/mL) multi-dose vial
55150-0314-01	Methylprednisolone acetate USP 400 mg 80 mg/mL vial
55150-0328-10	Naloxone HCl 0.4 mg/mL vial
55150-0327-10	Naloxone HCl 0.4 mg/mL vial
55150-0345-10	Naloxone HCl 1 mg/mL syringe
55150-0183-10	Nicardipine HCl 25 mg/10 mL vial
55150-0183-11	Nicardipine HCl 25 mg/10 mL vial
55150-0308-01	Olanzapine 10 mg vial
55150-0202-10	Pantoprazole sodium 40 mg vial
55150-0234-10	Polymyxin B sulfate 500,000 unit vial
55150-0388-01	Posaconazole 300 mg/16.7 mL vial
55150-0225-05	Rocuronium bromide 10 mg/mL vial
55150-0226-10	Rocuronium bromide 10 mg/mL vial
55150-0173-01	Sumatriptan succinate 6 mg/0.5 mL vial
55150-0173-05	Sumatriptan succinate 6 mg/0.5 mL vial
55150-0273-25	Thiamine HCl 100 mg/mL vial

55150-0228-10	Tigecycline 50 mg vial
55150-0470-06	Tobramycin sulfate 1.2 gram vial
55150-0385-01	Triamcinolone acetonide 40 mg/mL vial
55150-0384-01	Triamcinolone acetonide 40 mg/mL vial
55150-0471-10	Vancomycin hydrochloride injection 1.25 gram vial
55150-0472-10	Vancomycin hydrochloride injection 1.5 gram vial
55150-0370-24	Vasopressin 20 unit/mL vial
55150-0370-25	Vasopressin 20 unit/mL vial
55150-0235-10	Vecuronium bromide injection 10 mg vial
55150-0235-11	Vecuronium bromide injection 10 mg vial
55150-0236-20	Vecuronium bromide injection 20 mg vial
55150-0236-21	Vecuronium bromide injection 20 mg vial

Appendix 4. The EDSA Rapid Response Team

The information provided in this document was compiled on behalf of the End Drug Shortages Alliance (EDSA) Rapid Response Team (RRT) in collaboration with the Vizient® Center for Pharmacy Practice Excellence and the United States Pharmacopeia (USP).

The RRT is an EDSA work group aimed at addressing and mitigating drug supply chain disruptions. The RRT brings together a diverse group of stakeholder experts within the EDSA.

Formally established in late 2023, the RRT serves to identify, assess, and respond to pharmaceutical supply chain disruptions (ex. natural disasters, regulatory issues, manufacturing challenges or closures). Leveraging their collective clinical knowledge and analytical expertise, this dedicated work group is committed to providing timely information to all industry stakeholders across the pharmaceutical supply chain.

The RRT aims to proactively respond with strategic guidance and interventions by analyzing complex supply chain data, identifying vulnerable areas, and developing proactive strategies to mitigate risks, as such, the RRT supports EDSA's mission to end drug shortages.

If you are interested in learning more about the RRT, or are interested in joining the team, please email info@enddrugshortages.com.

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Formed in December 2021, the End Drug Shortages Alliance brings together health-systems, manufacturers, and other industry stakeholders across the supply chain who are dedicated to solving pharmaceutical supply challenges by collaborating to increase visibility, access, and advocacy. Collectively we will end drug shortages through focus on transparency, communication, quality, redundancy, and supply readiness to achieve measurable and sustainable results.

To learn more, please visit enddrugshortages.com or contact us at info@enddrugshortages.com.