Rhapsido® (remibrutinib) 25mg tablets

RHAPSIDO Epic® Tool Kit

The purpose of this tool kit is to provide a comprehensive guide for creation of an order set and integration of the RHP Start Form using best practice standards within the Epic system.

Key Sections:

- RHAPSIDO SmartSet
- Integration of RHAPSIDO Start Form Into Epic

Indication

RHAPSIDO® (remibrutinib) is indicated for the treatment of chronic spontaneous urticaria (CSU) in adult patients who remain symptomatic despite H1 antihistamine treatment.

Limitations of Use: RHAPSIDO is not indicated for other forms of urticaria.

Important Safety Information

Warnings and Precautions

- Risk of Bleeding: Mucocutaneous-related bleeding occurred in 9% of patients who received RHAPSIDO. Interrupt treatment with RHAPSIDO if bleeding is observed and resume if the benefit is expected to outweigh the risk. Interrupt treatment with RHAPSIDO for 3 to 7 days pre- and post-surgery or invasive procedures. Use of antithrombotic agents concomitantly with RHAPSIDO may further increase the risk of bleeding. Consider the benefits and risks of antithrombotic agents when used with RHAPSIDO. Monitor for signs and symptoms of bleeding
- The use of live and live-attenuated vaccines should be avoided in patients receiving RHAPSIDO

Please see Indication and Important Safety Information on page 9 and full Prescribing Information.

Considerations

- Specify the name of the existing SmartSet to be modified or the desired name for the new SmartSet to be created
- Identify the specific SmartGroup(s) where the modifications should take place. For example, a SmartSet can incorporate SmartGroups for medications, patient information, and follow-up visit time frames
- Include appropriate orders or laboratory tests, providing necessary order details

Create and Configure a New SmartGroup

1. In Hyperspace, open the SmartGroup Editor (search: SmartGroup) and create a new SmartGroup record. Click General Info from the table of contents
2. The name you gave the SmartGroup appears automatically in the Record name and Display name fields underneath the toolbar. In the Display name field, enter the title you want clinicians to see

Add Items to a SmartGroup

1. In Hyperspace, in the SmartGroup Editor (search: SmartGroup) select the SmartGroup you want to configure, if it is not already open
2. To add an item, click Add Item in the toolbar. Then, select the type of order or clinical content you want to add, such as Order
3. Select an item and click Accept. The item appears in the Configuration section with fields to customize its details in the SmartGroup
4. Edit the item's details as necessary. If you do not edit details for the item, the system looks to that item's record, such as a procedure record for details
5. To make an item selected by default when the clinician adds a SmartSet that contains the SmartGroup, select the check box that appears to the left of the item's name
6. To move an item up or down in the SmartGroup, select that item and click the Move Up or Move Down buttons in the toolbar. To remove an item, select that item and click the X button
7. Continue creating SmartGroups for each individual section of orders, medications, post-care notes, follow-up appointments, instructions, etc.

Important Safety Information (continued)

Adverse Reactions

- The most common adverse reactions (incidence ≥ 3%) were nasopharyngitis, bleeding, headache, nausea, and abdominal pain

Drug Interactions

- Remibrutinib is a CYP3A4 substrate and a P-glycoprotein (P-gp) inhibitor
- Avoid use of RHAPSIDO with strong or moderate CYP3A4 inhibitors. Concomitant use with a strong or moderate CYP3A4 inhibitor increases remibrutinib exposure, which may increase the risk of RHAPSIDO adverse reactions

Create a New SmartSet

1. In Hyperspace, open the SmartSet Editor (search: SmartSet)
2. In the Select a SmartSet window, do one of the following, depending on whether you are building from scratch or using a copy template:
   - If you are building from scratch, go to the Create tab, and create a new SmartSet record
   - If you are using a copy template, search for your copy template and open it. In the SmartSet Editor, click Save As to make a new copy of your copy template that you can then customize to build your new SmartSet or Order Set

Add SmartGroups to a section:

1. Click Add SmartGroup
2. Search for the SmartGroups you want to add

Continue the steps until the SmartSet contains all the sections and SmartGroups you wish to add.

Important Safety Information (continued)

Drug Interactions (continued)

- Avoid use of RHAPSIDO with strong or moderate CYP3A4 inducers. Concomitant use with a strong or moderate CYP3A4 inducer decreases remibrutinib exposure, which may decrease the efficacy of RHAPSIDO
- Monitor more frequently for adverse reactions when using RHAPSIDO with P-gp substrates where minimal concentration changes may lead to serious adverse reactions (eg, digoxin). Remibrutinib increases exposure of P-gp substrates, which may increase the risk of adverse reactions related to P-gp substrates
- No data are available on concomitant use of RHAPSIDO with anticoagulants. The concomitant use of RHAPSIDO and anticoagulants was not allowed in clinical studies. Use of the antiplatelet agents, acetyl salicylic acid at doses up to 100 mg daily or clopidogrel up to 75 mg daily, was allowed in the RHAPSIDO clinical studies

Review, Test, and Release SmartGroups and SmartSets

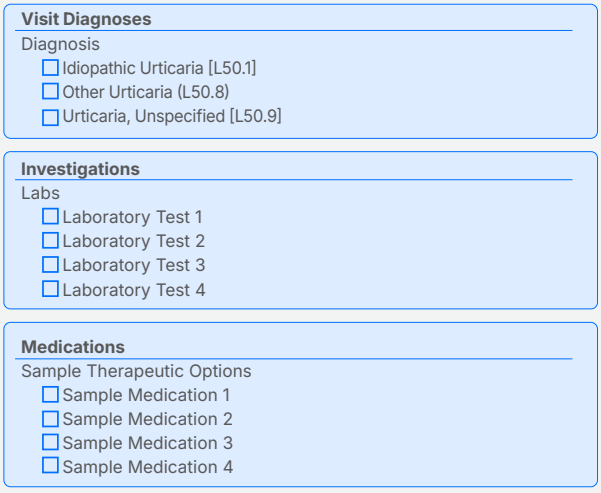
To ensure that the SmartGroups and SmartSets you create are useful to clinicians and contain the orders and clinical content clinicians need, send them to clinicians to review and test before releasing them for use in Hyperspace.

The content provided should be regarded as suggested material and should undergo thorough validation and review by clinical Subject Matter Experts. It is important to acknowledge that all clinical decisions ultimately rest with the healthcare providers (HCPs), and the examples furnished in this guide are not intended as definitive guidance for medical treatment.

Considerations for creation of a SmartSet specific to RHAPSIDO

Consider configuring laboratory tests and follow-up visits to evaluate for CSU per your institution's standard practices

Hypothetical CSU SmartSet



This image is intended for illustrative purposes only.

Consider configuring laboratory tests and follow-up visits to evaluate for (standing laboratory tests).

Important Safety Information (continued)

Use In Specific Populations

- There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to RHAPSIDO during pregnancy
- Avoid use of RHAPSIDO in patients with mild, moderate, or severe hepatic impairment (Child-Pugh Class A, B, and C). RHAPSIDO exposure is increased in these patients relative to patients with normal hepatic function

Link RHAPSIDO Start Form to an order in Epic (Optional)

Complete integration steps 1-3 before proceeding

1. Preparation

- Obtain the pre-configured **RHAPSIDO Start Form (PDF)** from Novartis (via Access & Reimbursement Manager or secure website)
- Save the form with a unique, descriptive name (eg, RHAPSIDO Start Form)
- Ensure administrative access to Epic to configure custom forms and document routing

2. Uploading the Form Into Epic

- Navigate to **EpicCare Administration → Document Types / Media Manager** (depending on build)
- Upload the RHAPSIDO PDF into the system's **form library**
- Assign a clear document type (eg, "Biologic Start Form – RHAPSIDO")
- Configure **permissions** so providers and designated staff (dermatology, rheumatology, specialty pharmacy teams) can access it

3. Mapping & Auto-Population (if enabled)

- Work with an Epic analyst to **map available patient chart data** (demographics, diagnosis codes, allergies, insurance information) to corresponding fields in the PDF
- Validate field mappings in a **test environment** before production deployment

4. Accessing the Form During a Visit

- In a patient chart, during a RHAPSIDO initiation encounter:
  1. Navigate to the **Visit Navigator / Encounter Tools**
  2. Select **Forms / Media Manager**
  3. Open the RHAPSIDO Start Form
  4. Review and complete blank fields
  5. Capture provider and patient signatures (via Epic's signature capture or imported PDF tool)
  6. Save as **Draft** to Patient Attachments until finalized

Important Safety Information (continued)

Warnings and Precautions

- Risk of Bleeding: Mucocutaneous-related bleeding occurred in 9% of patients who received RHAPSIDO. Interrupt treatment with RHAPSIDO if bleeding is observed and resume if the benefit is expected to outweigh the risk. Interrupt treatment with RHAPSIDO for 3 to 7 days pre- and post-surgery or invasive procedures. Use of antithrombotic agents concomitantly with RHAPSIDO may further increase the risk of bleeding. Consider the benefits and risks of antithrombotic agents when used with RHAPSIDO. Monitor for signs and symptoms of bleeding
- The use of live and live-attenuated vaccines should be avoided in patients receiving RHAPSIDO

5. Finalization & Faxing

- Once completed, mark the form as **Final**
- From **Chart Review → Media / Letters**, select the finalized RHAPSIDO Start Form
- Route via **Epic Fax Utility** to Novartis hub at **866-433-2300**
- Confirm RHAPSIDO is listed as a referral/fax contact under **Document Routing > Manage Referral Contacts**

6. Workflow Option: Task-Based Routing

- After provider orders RHAPSIDO initiation:
  - Create a **Task (Quick Task)** linked with the visit
  - Associate the RHAPSIDO Start Form (draft) with the task
  - Assign to **Biologic Coordinator / Specialty Pharmacy Queue**
  - Coordinator opens the task, completes remaining form fields, obtains signatures, finalizes, and faxes to Novartis

7. Testing & Validation

- Test the workflow in a nonproduction environment
- Validate:
  - Correct data mapping and pre-population
  - Signature capture workflow
  - Fax routing and delivery confirmation
- Train end users (providers, nurses, coordinators) on access, completion, and fax process

Important Safety Information (continued)

Adverse Reactions

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Drug Interactions

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- Avoid use of RHAPSIDO with strong or moderate CYP3A4 inhibitors. Concomitant use with a strong or moderate CYP3A4 inhibitor increases remibrutinib exposure, which may increase the risk of RHAPSIDO adverse reactions
- Avoid use of RHAPSIDO with strong or moderate CYP3A4 inducers. Concomitant use with a strong or moderate CYP3A4 inducer decreases remibrutinib exposure, which may decrease the efficacy of RHAPSIDO

Integration of RHAPSIDO Start Form into Epic

1. Preparation

- Confirm the RHAPSIDO Start Form PDF is uploaded and configured in Epic (via **Media Manager/ Document Type**)
- Verify the form has a clear document type (eg, Biologic Enrollment Form – RHAPSIDO) and proper routing rules (fax destination)

2. Build the RHAPSIDO Orderable

- Navigate to **Order Composer / Order Build** in Hyperspace or text environment
- Confirm the **medication order for RHAPSIDO (remibrutinib)** exists in the formulary with the correct dosing options
- If not present, create or request addition to the formulary

3. Create or Update Order Set

1. Go to **Epic → Clinical Content → Order Sets (OSQ records)**
2. Open the existing **Biologics Order Set** or create a new one (eg, RHAPSIDO Initiation Order Set)
3. Add the **RHAPSIDO medication** order to the order set

4. Link the Start Form to the Order Set

1. Within the Order Set, add an **Order Panel or SmartLink section** that points to the form
   - Use **Linked Documents / SmartForms** functionality
   - Associate the **RHAPSIDO Start Form document type** with the medication order
2. Configure **"When this order is placed, prompt to open the form"** behavior
   - This can be done using **Order Transmittal Triggers (OTR records)** or by adding a **Form Association** in the Order Set line item
3. Ensure the form launches either:
   - **Inline** within the ordering workflow, OR
   - **Available via hyperlink / embedded SmartLink** in the Order Set instructions

Important Safety Information (continued)

Drug Interactions (continued)

- Monitor more frequently for adverse reactions when using RHAPSIDO with P-gp substrates where minimal concentration changes may lead to serious adverse reactions (eg, digoxin). Remibrutinib increases exposure of P-gp substrates, which may increase the risk of adverse reactions related to P-gp substrates
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5. Routing & Tasking Setup

- Configure automatic **task creation** for the Biologics Coordinator when the form is generated
- Link the form with **fax routing rules** so that once finalized, it automatically appears in the appropriate fax work queue

6. Security & Permissions

- Assign **Order Set access** to the correct provider groups (dermatology, rheumatology, specialty pharmacy)
- Validate that only authorized users can edit or finalize the RHAPSIDO Start Form

7. Testing

- In a test environment (POC/TST):
  1. Open the RHAPSIDO Order Set
  2. Place the RHAPSIDO initiation order
  3. Confirm the Start Form automatically launches or is easily accessible
  4. Verify that patient demographics, insurance, and clinical data map correctly
  5. Confirm finalized form routes successfully to fax

8. Production Migration & End-User Training

- Move the Order Set and form linkage into **production via change control**
- Provide brief training or tip sheets showing providers where to find the form when ordering RHAPSIDO

End result: whenever a provider initiates RHAPSIDO from an Epic Order Set, the RHAPSIDO Start Form will automatically be available, ensuring consistent enrollment workflow.

Important Safety Information (continued)

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Please see full Prescribing Information, including Patient Information.

Novartis is not responsible for the implementation, testing, and ongoing operation of any EHR tools.

If you have any questions pertaining to the use of these guides, please refer to your internal IT/IS department. These tools are not designed for, and have not been demonstrated to meet, any accreditation requirements.

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