Rhapsido® (remibrutinib) 25mg tablets

RHAPSIDO EMA/ModMed® 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 EMA/ModMed system.

Key Sections:

- Configuring a Medication Order Set in EMA/ModMed
- Integration of RHAPSIDO Start Form into EMA/ModMed

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 7 and full Prescribing Information.

Configuring a Medication Order Set in EMA/ModMed

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Prerequisites

- Administrator or Super-User access to EMA/ModMed
- Knowledge of your practice's medication formulary and prescribing policies
- Access to Practice Settings and Order Set configuration tools
- (Optional) Test patient chart for validation before go-live

Step 1: Define Scope of the Order Set

1. Identify **clinical scenario(s)** the order set should cover
2. Decide whether the set will **include**:
   - Medications only
   - Medications + laboratory tests + follow-up tasks
   - Patient education handouts
3. Confirm **default values** (dose, route, frequency, duration) with providers/pharmacy to ensure safety and standardization

Step 2: Navigate to Order Set Configuration

1. Log in to EMA/ModMed with **administrator privileges**
2. From the main navigation:
   - Go to **Administration** (Practice Settings)
   - Select **Order Sets / Templates** (naming varies slightly depending on build version)
3. Click **New Order Set** (or Create Template if under template manager)

Step 3: Create the Order Set Framework

1. Enter **Order Set Name**
2. Add a **Category or Specialty tag** (eg, Internal Medicine, Dermatology)
3. Add a **Description/Notes**, so staff understand when to use this set
4. Set **Visibility & Permissions**: define which providers, roles, or facilities can use the set

Important Safety Information (cont)

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

Step 4: Add Medications

1. Select **Add Order >** Medication
2. Search for the medication by generic name (preferred to ensure formulary compliance)
3. Configure **default prescribing** parameters:
   - Strength
   - Route
   - Frequency
   - Duration
   - Refills
4. Decide whether defaults are required (locked in) or editable by the provider
5. Repeat steps for each medication needed in the set

Step 5: Add Related Orders (Optional)

1. Laboratory tests/Diagnostics: **Add laboratory tests** commonly ordered with the medication
2. Patient Education: Attach standard PDFs, counseling text, or instructions
3. Follow-up Tasks/Reminders

Step 6: Save and Validate

1. **Save** the new Order Set with a unique name
2. Assign to relevant **clinical workflows**:
   - Visit types (New Patient, Follow-Up)
   - Conditions (Problem List triggers)
3. Open a test patient chart **>** go to Orders **>** select the **New Order Set**
4. Verify that:
   - Medications pre-populate correctly
   - Dosage/frequency defaults are safe and accurate
   - Linked laboratory tests, instructions, or tasks appear

Important Safety Information (cont)

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

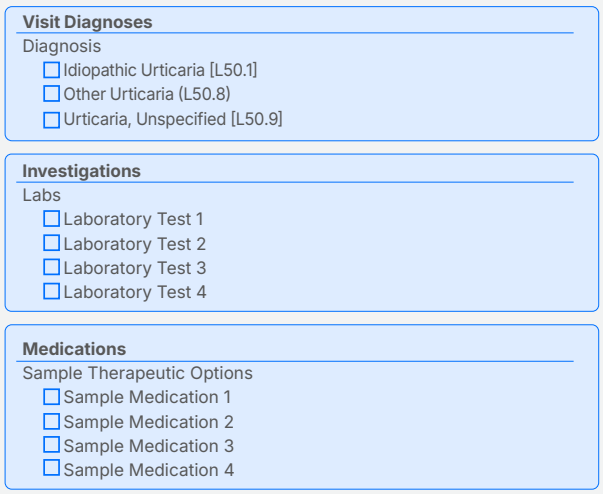
Step 7: Deploy to Production

1. Once validated, notify providers/staff that the new **Order Set** is available
2. Provide training/cheat sheets showing when and how to use the set
3. Monitor usage for the first 30 days:
   - Gather feedback from clinicians
   - Adjust defaults if prescribing patterns differ

Considerations for creation of a specific order set for RHAPSIDO®

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

Hypothetical CSU Order Set



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 (cont)

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

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Instructions for Integrating the RHAPSIDO Start Form Into the EMA/ModMed EMR

Background

The RHAPSIDO Start Form is a static PDF enrollment and prescription form that can be integrated into EMA/ModMed. Structured patient data from EMA/ModMed can be mapped to the form to pre-populate fields, reducing manual entry. Once mapped and completed, the form can be finalized and faxed to the RHAPSIDO hub. Administrator privileges are required to upload and configure the form.

Step 1: Upload the RHAPSIDO Start Form

1. Obtain the pre-configured RHAPSIDO Start Form PDF from your Access & Reimbursement Manager (ARM) or the Novartis secure website
2. Save the PDF with a unique name (eg, "RHAPSIDO Start Form") to your workstation or network drive
3. In EMA/ModMed (with administrator privileges):
   - Go to **Practice Settings > Firm Forms > Manage PDFs**
   - Click **Upload PDF** and add the RHAPSIDO form
   - Assign a **title**, **category**, and **permissions** for the appropriate providers and facilities

Step 2: Access the Form During a Visit

Option 1: Direct Access

1. Open the patient's chart
2. Select the **RHAPSIDO Initiation Visit**
3. From the **Visit Overview** window, choose **PDF Manager**
4. Select the uploaded **RHAPSIDO Start Form**
5. Review the auto-populated data and complete remaining fields
6. Obtain provider and patient **signatures** (via iPad)
7. Save as **Draft** if still in progress (this adds it to patient attachments)
8. When complete, click **Finalize**
9. From **Patient Attachments**, select the form and fax to **866-433-2300**

Note: RHAPSIDO may need to be added to your site's **Manage Referral Contacts** for fax routing.

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Step 3: Task-Based Workflow (Optional)

Option 2: Create a Task

1. After the provider initiates RHAPSIDO in the chart, click **Create Task** (top right)
2. Select **Quick Task > Initiate Biologic**
   - If no Quick Task exists, create one:
     - Go to **Task Menu > Manage Quick Tasks > New Quick Task**
     - Fill required fields and save
3. In the **Create New Task** window:
   - Add "RHAPSIDO" in the Notes
   - Link the task to the visit and the draft RHAPSIDO form from **Attachments**
   - Save
4. The task will appear in the biologic coordinator's queue
5. The coordinator can open the linked visit and complete the RHAPSIDO Start Form
6. Provider and patient sign electronically
7. Click **Finalize**
8. Fax from **Patient Attachments** to **866-433-2300**

Important Safety Information (cont)

Adverse Reactions

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Drug Interactions

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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.

For more information on how the Novartis Health Information Technology team can collaborate with your organization to identify shared priorities, please email: HIT.Novartis@novartis.com

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